



**EXEMPT JOB OPPORTUNITY****Wyeth**

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<b>POSTING DATES:</b>	9/22/2004-9/28/2004	<b>JOB#:</b>	WPL908210
<b>JOB TITLE:</b>	Manager, Manufacturing Support (PPU1)	<b>GRADE:</b>	Up to EX12
<b>COMPANY:</b>	Pharma	<b>HOURS:</b>	8:00 AM - 4:30 PM
<b>LOCATION:</b>	NY - Pearl River	<b>FAX:</b>	845-602-5375
<b>PAPER BIDS TO:</b>	Patti Verhasselt		
<b>POSITION REPORTS TO:</b>	Andrew Espejo	<b>TITLE:</b>	PPU Lead, Manufacturing Operations PPU#1
<b>HR REPRESENTATIVE:</b>	Patti Verhasselt		

**POSITION DESCRIPTION:**

As Manager, Manufacturing Support (PPU1), you will manage the Department by communicating and tracking objectives to staff. You will provide guidance to staff to facilitate successful completion of objectives. You will continually improve the Department's service by adapting / expanding staff responsibilities to changing needs. You will support capital project initiatives with the design, safety reviews, construction, validation and startup. You will coordinate activities between Technical Services, production, engineering and maintenance to ensure final product makes or exceeds quality measures. You will monitor departmental production engineering projects to ensure timely completion. You will provide primary validation and engineering support to Manufacturing operations through detailed capacity analysis, throughput studies, raw material and WIP strategies. You will identify process improvements through debottlenecking initiatives and evaluate existing equipment along with new technologies. You will manage process validation scientists to provide daily process improvement, minor validation and troubleshooting services to the manufacturing and packaging depts. You will interface with the Technical Support directorate. You will ensure compliance with cGMPs, environmental and OSHA regulations as well as company safety guidelines. You will be responsible for ensuring implementation of training programs covering job skills, safety, regulatory, compliance and other pertinent issues. You will manage one Technical writer whose function is to assist manufacturing supervision in the timely completion of Standard Operating Procedures creation and revisions. You will be knowledgeable of GMPharma databases.

**OTHER COMMENTS:**

You must have a BS in Engineering. MBA preferred. Pharmaceutical experience preferred.

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Employees at locations in the normal posting area will be interviewed prior to employees at other Wyeth sites.



# ENGINEER STATUS PROJECT REPORT

LCH Centrum Production (Train #1)

September 17, 2003

Project	Date Received	Purpose	Description	Status																																		
Continuous Tablet Coater Action Items	1/03	Perform all tasks associated with safe and proper use of the Continuous Coater.	<div>1. CTC Verification Process:</div> <div><ul style="list-style-type: none"><li>Hold a meeting on all three shifts detailing the equipment involved in the verification process, in order to correct passed mistakes as well as the pass/fail percentage of all equipment involved in the process. The pass fail rate for each unit is listed below:</li></ul></div> <table><thead><tr><th>Equipment</th><th>Passing Percentage (%) Period (7/28/02-1/8/03)</th></tr></thead><tbody><tr><td>Coater #1</td><td>50%</td></tr><tr><td>Coater #2</td><td>44%</td></tr><tr><td>*IBEX Gear Pumps</td><td>50%</td></tr><tr><td>Solution Tank 19A</td><td>13%</td></tr><tr><td>Solution Tank 20B</td><td>6%</td></tr><tr><td>Solution Tank 21A</td><td>13%</td></tr><tr><td>Solution Tank 22B</td><td>19%</td></tr><tr><td>Vac-U-Max 19A</td><td>88%</td></tr><tr><td>Vac-U-Max 20B</td><td>94%</td></tr><tr><td>Vac-U-Max 21A</td><td>81%</td></tr><tr><td>Vac-U-Max 22B</td><td>94%</td></tr><tr><td>Inlet Conveyor Belt</td><td>100%</td></tr><tr><td>Conveyor Belt A</td><td>100%</td></tr><tr><td>Conveyor Belt B</td><td>94%</td></tr><tr><td>Conveyor Belt C</td><td>94%</td></tr><tr><td>Weigh Belt</td><td>94%</td></tr></tbody></table> <div><p>* Will not be part of the verification process</p><ul style="list-style-type: none"><li>Manage all activities in order to pass three consecutive inspections. Verifications will consist of visual inspection, examination of all cleaning checklists to ensure proper and complete execution and the testing for the removal of any cleaning agent used to clean CTC equipment. Technical Service personnel will conduct the inspection process activities.</li></ul></div>	Equipment	Passing Percentage (%) Period (7/28/02-1/8/03)	Coater #1	50%	Coater #2	44%	*IBEX Gear Pumps	50%	Solution Tank 19A	13%	Solution Tank 20B	6%	Solution Tank 21A	13%	Solution Tank 22B	19%	Vac-U-Max 19A	88%	Vac-U-Max 20B	94%	Vac-U-Max 21A	81%	Vac-U-Max 22B	94%	Inlet Conveyor Belt	100%	Conveyor Belt A	100%	Conveyor Belt B	94%	Conveyor Belt C	94%	Weigh Belt	94%	<div>1) Status.</div> <div><ul style="list-style-type: none"><li>Complete. Three meetings held on 3/6/2003.</li></ul></div>
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Weigh Belt	94%																																					
			<ul style="list-style-type: none"><li>Complete. All equipment passed three consecutive verification procedures on 3/8, 3/15 and 3/22/03.</li></ul>																																			

2553

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# ENGINEER STATUS PROJECT REPORT

LCH Centrum Production (Train #1)

September 17, 2003

Continuous Tablet Coater Action Items (Continued)	1/03	Perform all tasks associated with safe and proper use of the Continuous Coater.		
			<p>2. Vac-U-Max access (platform/ladders):</p> <ul style="list-style-type: none"> <li>• A meeting must be held with Bishnu Joarder, Andy Sakell and Susan Rera to discuss operator access of the Vac-U-Max.</li> <li>• Send request to engineering to the attention of Bishnu Joarder</li> <li>• Design platform</li> <li>• Write change control and justification</li> <li>• Circulate job order for approval</li> <li>• Install platform</li> <li>• Cut and polish holes through platform for Vac-U-Max hoses</li> <li>• Install platform ladders</li> <li>• Inspect platform and have ORR conducted by Safety</li> <li>• Respond to all ORR items</li> <li>• Close Change Control</li> </ul> <p>3. CTC PMO Responsibility/Technology Transfer</p> <p>Conduct the following activities in order to transfer CTC execution from Thomas Engineering to Wyeth Pharmaceuticals</p> <ul style="list-style-type: none"> <li>• Verify the model and serial numbers for all equipment on CTC #1, CTC#2, Air Handlers and Dust Collectors by visual inspection</li> <li>• Inspect all PMO procedures for proper procedure and complete equipment testing. This involves three PMO documents i.e. Mechanical, Electrical and Instrumentation PMO documents</li> </ul> <p>4. CTC-Spare Parts Assessment Team</p> <p>Establish a spare parts list for the CTC system. Perform the following tasks in order to establish a spare parts list for all CTC equipment.</p> <ul style="list-style-type: none"> <li>• Provide recommended spare parts list to maintenance</li> <li>• Determine critical and non critical parts for each equipment</li> <li>• Inspect final list with Maintenance personnel</li> <li>• Order parts</li> </ul>	<p>2) Status</p> <ul style="list-style-type: none"> <li>• Complete. A platform will be designed and built</li> <li>• Complete.</li> <li>• Complete.</li> <li>• Complete</li> <li>• Complete</li> <li>• Complete</li> <li>• Complete</li> <li>• Complete</li> <li>• Complete</li> <li>• Complete</li> </ul> <p>3) Status</p> <ul style="list-style-type: none"> <li>• Complete. All equipment verified</li> <li>• Complete. All PMO procedures inspected</li> </ul> <p>4) Status</p> <ul style="list-style-type: none"> <li>• Complete.</li> <li>• Complete.</li> <li>• Complete.</li> <li>• Complete.</li> </ul>

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# ENGINEER STATUS PROJECT REPORT

LCH Centrum Production (Train #1)

September 17, 2003

Continuous Coater Project Action Items (Continued)	1/03	Perform tasks to remediate startup issues with the Continuous Coater.	5. CTC-Dust Collector Issues: 1/24/03: Meeting held to address dust collector issues i.e. freezing of the filters especially in CTC-dust collector #2. The following action items came as a result of the meeting: <ul style="list-style-type: none"><li>• Remove Spray System handle from unit</li><li>• Instruct operators not to spray water in the duct-work above the unit</li><li>• Remind supervisors and operators to preheat the dust collector unit prior to drying the unit</li><li>• Create reminder list of actions operators should not perform</li></ul> 9/03: Changed all CTC dust collector actuator fittings in order to prevent the unit from displaying false pressure readings due to faulty fittings <ul style="list-style-type: none"><li>• Discuss situation with instrumentation mechanics</li><li>• Initiate work order request</li></ul> 6. CTC Bins <ul style="list-style-type: none"><li>• Address problem with bin knobs falling from CTC bin valves. 3/4/03: Called A. Rosencranz along with D. Dooley (Tinsmith) to address the issue of knobs falling from bin valves. Replacement parts costly. Repairs will be made in-house in order to fix this problem</li><li>• Replace all bin wheels</li></ul> 7. Equipment ordering. The following equipment must be ordered: <ul style="list-style-type: none"><li>• Roughing Filters for CTC#1</li><li>• Conveyor Belt Speed Sensors</li><li>• Vac-U-Max mufflers</li><li>• Vac-U-Max inlet chutes</li><li>• Vac-U-Max socks</li><li>• CTC Bin Valve Parts</li></ul>	5) Status  Complete. Complete. Complete Complete Complete
Howard Henry Production Engineer Manufacturing				6) Status <ul style="list-style-type: none"><li>• Complete. WO#335543</li></ul> 7) Status <ul style="list-style-type: none"><li>• Complete via WO# 275130, 287263, 297083</li><li>• Ordered and replaced</li><li>• Ordered and received</li><li>• Ordered and received</li><li>• Ordered and received</li><li>• Ordered and received</li></ul>

2555

# ENGINEER STATUS PROJECT REPORT

LCH Centrum Production (Train #1)

September 17, 2003

Gap Strategy Assessment	2/03	Perform all duties in order to properly categorize equipment listed under assessment.	This assessment is part of a plant wide initiative, analyzing all equipment in order to achieve 21CFR Part 11 compliance. The following units must be assessed utilizing the form provided by the Gap Strategy Assessment Representative: <ul style="list-style-type: none"> <li>• PC#7</li> <li>• PC#8</li> <li>• CTC#1</li> <li>• CTC#2</li> </ul>	1) Assessment status is listed below: <ul style="list-style-type: none"> <li>• Complete</li> <li>• Complete</li> <li>• Complete</li> <li>• Complete</li> </ul>
CTC Single Pass Project	5/03	Perform all duties in order to successfully complete this project by 12/31/03	The objective of the CTC Single Pass Project is to increase the CTC tablet coating process time by a minimum of 50%. This will be done by decreasing the tablet throughput, coating tablets in the CTC system in a "single" pass as opposed to using two coaters for two coating applications. <ol style="list-style-type: none"> <li>The following tasks must be performed in order to complete this task: <ul style="list-style-type: none"> <li>• Write solution tank functionality memo</li> <li>• Resolve maintenance related issues that could possible effect project <ul style="list-style-type: none"> <li>◦ Bent Baffle issue: effects tablet bed height and throughput</li> <li>◦ Inlet Plenum issue: affects proper heating</li> <li>◦ Resolve slow temperature heating issue (CTC-AHU#1)</li> </ul> </li> <li>• Check into installation of access door in the duct-work</li> <li>• Revise Cleaning SOP's creating specific CTC-Single Pass SOP's</li> <li>• Review and revise PID documents supplied by Sear Brown and Sikorski representative R. Hoffman</li> <li>• Remove and install gun arms for test. After test reinstall old gun arms</li> <li>• Order listed spare parts for Spectrum spray arm unit <ul style="list-style-type: none"> <li>◦ 64 Spray bar o' ring</li> <li>◦ 20 Manifold sections</li> <li>◦ 8 spray gun bodies .75 mm</li> <li>◦ 32 spray gun needles .75 mm</li> </ul> </li> </ul> </li> </ol>	1) Status for each item is listed below: <ul style="list-style-type: none"> <li>• Complete.</li> <li>• All items completed via work order requests <ul style="list-style-type: none"> <li>◦ Complete</li> <li>◦ Complete</li> <li>◦ Complete</li> </ul> </li> <li>• Complete.</li> <li>• Ongoing. SOP's revised once final parameters are established</li> <li>• Complete.</li> <li>• Complete. Done each time via work request</li> <li>• Complete. All parts ordered and received</li> </ul>

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# ENGINEER STATUS PROJECT REPORT

LCH Centrum Production (Train #1)

September 17, 2003

Review Team Meeting	9/03	Perform all duties required to resolve all outstanding issues associated with CTC batch accountability.	1. Chair of the CTC Review Team Meeting Committee. Perform the following tasks as chairman of this committee: <ul style="list-style-type: none"> <li>Coordinate and conduct weekly meetings</li> <li>Write meeting minutes weekly and distribute to all attendees</li> <li>Analyze Weigh belt progress during coating process</li> <li>Analyze PLC/HMI System Loop check</li> <li>Resolve AHU and Dust Collector shutdown issues</li> <li>Evaluate current batch calculation methods</li> <li>Modify PMO</li> </ul>	1) Status is listed below: <ul style="list-style-type: none"> <li>Complete</li> <li>Complete</li> <li>Complete</li> <li>Complete</li> <li>Complete</li> <li>Complete</li> </ul>
IR Commitments	Ongoing	Various commitments received during various production excursions	<ol style="list-style-type: none"> <li>Commitment #26381: The CTC temperature went out of range. <ul style="list-style-type: none"> <li>Due date: 5/30/03</li> </ul> </li> <li>Commitment #30159: Install door sweep on Mechanical Room 112-300. <ul style="list-style-type: none"> <li>Due date: 12/31/03</li> </ul> </li> <li>Commitment #30213: Replace broken drain screen and replace pipe in Mechanical Room 112-300. <ul style="list-style-type: none"> <li>Due date: 7/25/03</li> </ul> </li> <li>Commitment #30218: Repair and paint damaged coving in Passageway 112-300A <ul style="list-style-type: none"> <li>Due date: 7/25/03</li> </ul> </li> <li>Commitment #32981: Review the feasibility of calibrating the Weigh Belt weekly due to OOS for batch 04451-1025 <ul style="list-style-type: none"> <li>Due date: 9/30/03</li> </ul> </li> <li>Commitment #35670: Study best way to secure Iris Valve to bins in PC#8. <ul style="list-style-type: none"> <li>Due date: 1/31/04</li> </ul> </li> <li>Commitment #37198: Initiate system to replace gear of IBEX pumps <ul style="list-style-type: none"> <li>Due date: 1/15/04</li> </ul> </li> <li>Provided documentation to help with the closure of commitments: <ul style="list-style-type: none"> <li>CIP-100 (Pace Report Evaluation) Memo</li> <li>Alconox Usage Memo</li> <li>CTC heating excursion Memo</li> </ul> </li> </ol>	<ol style="list-style-type: none"> <li>Complete. Closed 5/30/03</li> <li>Complete. Closed (10/31/03)</li> <li>Complete. Closed (7/14/03)</li> <li>Complete. Closed (7/11/03)</li> <li>Complete. Closed (9/18/03)</li> <li>In process</li> <li>In process</li> <li>All information researched and documents written. <ul style="list-style-type: none"> <li>Complete</li> <li>Complete</li> <li>Complete</li> </ul> </li> </ol>

2557

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# ENGINEER STATUS PROJECT REPORT

LCH Centrum Production (Train #1)

September 17, 2003

Change Control Procedures	Ongoing	Initiation, Closure and Cancellation of Change Control Procedures	
1) CCP 2002-2613 "Modify Vac-U-Max PMO# 47186"	• Approved 10/02.	1) Change complete. Closed 12/14/02	25
2) CCP 2002-2615 "Installation of Vac-U-Max platforms:	• Approved 12/02	2) Work completed. CCP Closed 5/23/03	25
3) CCP 2002-1864 "Salvage scale from PMO 57273 and Maximo"	• Initiated by Gary Baisley	3) Work completed. Closed 6/18/03	
4) CCP 2002-1164 "Modification of PMO for 14 hand held micrometers"	• Initiated by Gary Baisley	4) Work completed. Closed 10/2/03	
5) CCP 2003-145 "Rerouting of Compressed Air Filter for CTC#2"	• Approved 1/20/03. Due 3/03	5) Work completed. Closed 1/30/03	
6) CCP 2003-212 "Removal of Drying Inlet Temperature Criteria from the SOI"	• Approved 3/03 Due 6/03	6) Work completed. Closed 4/30/03	
7) CCP 2003-2040 "Revision of PMO 47179"	• Approved 10/03. Due 12/03	7) Work completed. Closed 11/7/03	
8) The following CCPs were canceled:		8) All CCPs were canceled due to equipment and room validation issues. CCPs were canceled on 6/12/03 and 6/17/03.	
1. Welding of damaged mixing plows (6/4/03)	Supervise activities associated with repairing of the damaged plows.	1) Complete 6/6/03. Stayed until all activities were done.	
2. Littleford-10K Dust Collector Study (5/03)	Organize and communicate all activities associated with the	2) Progress on each activity is listed below:	

Howard Henry  
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Mr. Facturing

# ENGINEER STATUS PROJECT REPORT

## LCH Centrum Production (Train #1)

September 17, 2003

2559

			<p>successful completion this task.</p> <ul style="list-style-type: none"> <li>• Fax batch record information to Carlene Bassell</li> <li>• Discuss study plan with MEGS dust removal service representative</li> <li>• Communicate information to all supervisors and management staff</li> </ul> <p>3. Littleford Blender Electric Failure Remediation and Fike Relocation (1/03): Meeting held 3/11/03: The following activities must be performed in order to resolve circuit breaker tripping problems during the jog and mixing portion of the operation and in order to increase operator safety and protection from potential dust explosion during the blending process.</p> <ul style="list-style-type: none"> <li>• Reset sub-station breaker with Frank Gurfert (EE)</li> <li>• Assist in the determination of proper Fike Canister location</li> <li>• Assist in the determination of proper Fike Sensor location</li> <li>• Determine critical equipment routing installation locations and proper routing</li> </ul>	<ul style="list-style-type: none"> <li>▪ Complete. Faxed on 5/22</li> <li>▪ Complete</li> <li>▪ Complete</li> </ul> <p>(3) Progress on each activity is listed below:</p> <ul style="list-style-type: none"> <li>▪ Complete</li> <li>▪ Complete</li> <li>▪ Complete</li> </ul>
Ergonomics Team	3/03	Study all situations throughout manufacturing and make effect ergonomic changes	<p>3/14/03: First meeting held. Team members discussed ergonomic changes that needed to be made throughout the plant, that is, the Littleford 10K Blender Area, Compression - Fette Areas and the CTC Suite. The following Action Items must be addressed in the up-coming months:</p> <ol style="list-style-type: none"> <li>1. Littleford-10K: <ul style="list-style-type: none"> <li>• Platform/dump sink difficult to move</li> <li>• Dump sink positioning issues</li> <li>• Best Shaker powder distribution issues</li> <li>• Best Shaker wheels issues. Wheels are inadequate in moving the Shaker and become flat under the weight of the unit</li> </ul> </li> <li>2. Compression-Fette 3200 Area <ul style="list-style-type: none"> <li>• Bin moving issues</li> <li>• Change bin wheels</li> </ul> </li> <li>3. CTC Area</li> </ol>	<p>All issues addressed. Some items will require a study plan for resolution. The status of each item is listed below:</p> <ol style="list-style-type: none"> <li>1. Littleford 10K: <ul style="list-style-type: none"> <li>▪ Complete: Platform cannot be separated due to size and weight of the unit</li> <li>▪ Addressed: SS Polishing and not the angle appeared to be the issue. Sink polishing will increase with more use. See analysis above</li> <li>▪ Wheels assessed. Maintenance will contact manufacture for</li> </ul> </li> </ol>

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# ENGINEER STATUS PROJECT REPORT

LCH Centrum Production (Train #1)

September 17, 2003

			<ul style="list-style-type: none"> <li>• Drum movement issue</li> </ul>	<p>2560</p> <ul style="list-style-type: none"> <li>suggestion of better wheels</li> <li>2. Compression-Fette Area.               <ul style="list-style-type: none"> <li>▪ Chart Caddy ordered.</li> <li>New non-skid pad installed W/O#343445-6.</li> <li>Broken ignitions replaced with more durable ignition with sturdy keys.</li> <li>▪ All bin wheels replaced.</li> </ul> </li> <li>3. CTC Area:               <ul style="list-style-type: none"> <li>▪ Ongoing: Committee will be assembled to address these issues.</li> </ul> </li> </ul>
Manufacturing Support	1/03	Provide general support to all areas throughout manufacturing	<p>Continue to provide support to areas throughout the year performing the tasks listed below:</p> <ol style="list-style-type: none"> <li>1. Maintenance Zone Checklist: Assist supervisors in fulfilling the weekly requirement to analyze and repair areas for specific Maintenance zone assignments. Perform the following activities associated with this task:               <ul style="list-style-type: none"> <li>• Inspect area with supervisor in order to initiate the appropriate corrective action</li> <li>• Initiate work order requests</li> <li>• Communicate work order request number to supervisor so that number can be logged unto Zone Checklist form.</li> </ul> </li> <li>2. Central Storage / Set-Up Shop Area               <ul style="list-style-type: none"> <li>• Initiate work order requests to support the general maintenance of the area</li> <li>• Assist in scheduling PMO execution for equipment located in the area, i.e. Hardness testers, balances, micrometers and compression machines</li> <li>• Assist in supporting all equipment by initiating repair requests</li> </ul> </li> </ol>	<ol style="list-style-type: none"> <li>1. All activities completed weekly in order to fulfill this requirement               <ul style="list-style-type: none"> <li>▪ Area inspected as needed on a weekly basis</li> <li>▪ Work order requests furnished as needed</li> <li>▪ Information communicated via e-mail or by phone</li> </ul> </li> <li>2. Support ongoing. Status is listed below:               <ul style="list-style-type: none"> <li>▪ Ongoing. Work orders placed as needed</li> <li>▪ Ongoing. PMO procedures scheduled.</li> <li>▪ Supported equipment e.g. Stokes 754</li> </ul> </li> </ol>

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*LCH Centrum Production (Train #1)*

- Conduct assessments for the modification of equipment located in the area

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| <p>3. Fette-3200 Compression Machines</p> <p>Assist in the determination of effective corrective actions to help resolve the following issues</p> <ul style="list-style-type: none"> <li>• <i>Electrical Spiking Issue: 3/17/03:</i> Contacted Frank Gufert regarding this issue. Suggested that a power conditioner should be used to analyze the problem and that Fette also be contacted. 4/7/03: Paul Mueller made aware of the problem. He will provide a detailed summary regarding voltage feed/spiking issue</li> <li>• Powder loss issues: FDA approved tape initially installed to resolve this issue. QA representative Farooq Moatter ordered that the tape be removed. Maintenance contacted to provide alternative. Gasket material installed</li> <li>• Gearbox powder retention issues. This problem occurs because of the powder loss.</li> <li>• Provide extended assistance during the loss of F. Abatangelo and the training of compression supervisor M. Collorafi. Assisted in covering the area helping to resolve washroom issues (WO#334526), and compression shop damage (WO#342686)</li> </ul> | <p>3. Support ongoing. Status is listed below:</p> <ul style="list-style-type: none"> <li>• Complete. Awaiting final report from Paul Mueller</li> </ul>  |
| <p>4. QA Audit Item Assessment</p> <p>Pre-inspect audit areas and assist supervisors in assessing appropriate corrective actions in order to address various QA audit action items</p> <ul style="list-style-type: none"> <li>• Walked the Littleford-10K area with supervisor Keith Crump in order to address the following QA audit action items: <ul style="list-style-type: none"> <li>▪ Loose floor drain</li> <li>▪ Loose grating on wall</li> <li>▪ Paint room</li> </ul> </li> </ul>  | <p>4. Status listed below:</p> <ul style="list-style-type: none"> <li>▪ Gaskets installed (WO# 334244, 335142-4). Will be observed to establish if gaskets should be used permanently</li> <li>▪ Modified one gearbox. Will be checked</li> <li>▪ Complete. Assistance provided and will continue as needed.</li> </ul> |
|   | <ul style="list-style-type: none"> <li>▪ Complete. WO#315169</li> <li>▪ Complete. WO#314662</li> <li>▪ Complete. WO#315170</li> </ul>   |

# ENGINEER STATUS PROJECT REPORT

*LCH Centrum Production (Train #1)*

September 17, 2003

			<p>5. Hurricane Isabel Preparedness Committee</p> <ul style="list-style-type: none"> <li>• Provide a Action List for equipment and areas throughout the manufacturing area</li> <li>• Work with other committee members to determine safe shutdown and re-start methods for equipment and areas throughout the plant</li> </ul> <p>6. Schedule all departmental PMO procedures insure all PMO procedures are conducted as scheduled causing minimum impact to production demands.</p> <p>The following tasks must be completed in order to achieve this task:</p> <ul style="list-style-type: none"> <li>• Attend scheduled PMO meetings</li> <li>• Communicate PMO to department staff managers, coordinators and supervisor</li> <li>• Respond to PMO list monthly via e-mail providing execution time period</li> <li>• Follow-up with maintenance personnel to ensure complete execution</li> </ul> <p>7. Communicate Manufacturing and Plant shutdowns. Ensure effective communication occurs throughout the manufacturing areas during plant shutdowns. 2/10/03: AV#8 and all AHUs went down due to power failure. Stayed at plant until power returned</p> <p>The following tasks must be completed in order to complete this task:</p> <ul style="list-style-type: none"> <li>• Assess type of shutdown</li> <li>• Contact initiator in order to establish affected areas</li> <li>• Schedule shutdown around manufacturing demands</li> <li>• Communicate information to all affected areas</li> </ul>	<p>5. Status listed below:</p> <ul style="list-style-type: none"> <li>• Complete. Action Plan provided at the meeting.</li> <li>• Complete. Worked with other committee members assessing all equipment</li> </ul> <p>6. Status listed below:</p> <ul style="list-style-type: none"> <li>• Complete. Meeting attended monthly</li> <li>• Complete. Information communicated.</li> <li>• Complete. Responded to all e-mail requests</li> <li>• Complete. No PMO procedures overdue</li> </ul> <p>7. Status listed below:</p> <ul style="list-style-type: none"> <li>• All tasks must be completed each time a shutdown is scheduled.</li> </ul>
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Howard Henry  
Production Engineer  
Manufacturing

**ENGINEER STATUS PROJECT REPORT***LCH Centrum Production (Train #1)*

September 17, 2003

			<p>8. Purified water hose assessment committee Participate in analyzing and correcting all issues associated with purified water hoses currently in use.</p> <ul style="list-style-type: none"> <li>• Indicate rooms that will require purified water hoses</li> <li>• Determine location of purified hose stand(s) in designated rooms</li> </ul> <p>9. Blender Timer Printout Support</p> <ul style="list-style-type: none"> <li>• Provide printouts for non-legible readings for all equipment throughout the area equipped with Blender timers</li> </ul> <p>10. Initiate Maximo requests throughout the plant for all areas.</p> <p>Areas include but not limited to Bathrooms, Elevators, Hallways, all Mechanical Rooms, all Blending Rooms, all Coating areas and equipment, all Compression rooms and equipment, Inspection Areas, Warehouses, Washrooms, Weigh Rooms and Office Areas.</p> <ul style="list-style-type: none"> <li>• Attend weekly scheduling meetings for execution updates</li> <li>• Clear all WQAR (Awaiting QA review) backlogs</li> </ul> <p>11. Attend bi-weekly Customer Service Meetings. Meetings are intended to provide focused attention on manufacturing needs. The following tasks have been generated as a result of these meetings:</p> <ul style="list-style-type: none"> <li>• Verification of CTC #1 and CTC #2 PMO instrumentation list</li> <li>• CTC Spare Parts List</li> <li>• Fette electrical voltage/spiking issue</li> </ul>	<p>8. Status listed below:</p> <p>2563</p> <ul style="list-style-type: none"> <li>• Complete.</li> <li>• Complete.</li> </ul> <p>9. Status listed below:</p> <ul style="list-style-type: none"> <li>• Ongoing. Printouts provided for supervisors from all three Trains</li> </ul> <p>10. Status listed below:</p> <p>Maximo requests are ongoing. Over 700 (727) Maximo requests made.</p> <ul style="list-style-type: none"> <li>• Complete. Meeting attended weekly</li> <li>• Complete. No WQAR backlog as of 10/03</li> </ul> <p>11. Status listed below:</p> <ul style="list-style-type: none"> <li>• All items addressed and completed</li> </ul>
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Howard Henry  
Production Engineer  
Manufacturing

Wyeth Ayerst Pharmaceuticals  
Train 1 2003 Performance Objectives  
Howard Henry, Production Engineer / Train 1

Safety	Q1	Q2	Q3	Q4
<ul style="list-style-type: none"> <li>Participate in routine audits</li> </ul>	<p>Provide support for supervisors who are audited by assigning work order numbers to audit items. Follow up with maintenance in order to ensure those work orders are completed before commitment date deadlines</p> <p>OSHA Recordable rate for 1Q03 was 1.1</p>	<p>Provide support for supervisors who are audited by assigning work order numbers to audit items. Follow up with maintenance in order to ensure those work orders are completed before commitment date deadlines</p> <p>OSHA Recordable rate for 2Q03 was 1.6</p>	<p>Provide support for supervisors who are audited by assigning work order numbers to audit items. Follow up with maintenance in order to ensure those work orders are completed before commitment date deadlines</p> <p>OSHA Recordable rate for 3Q03 was 1.6</p>	
<ul style="list-style-type: none"> <li>Achieve OSHA Recordable Case Rate of 3.5</li> </ul>	<p>Member of the ergonomic committee. Pursue and perform action items that burgeon as the result of this meeting. Provide support, advice and feasibility of the suggestions set forth by the committee</p> <p><u>Benefits:</u> Safety, fewer MLOA, operator collaboration, cost savings.</p>	<p>Assessed Littleford 10K issues dealing with powder flow. Team continues to meet with core team members and rotate in a cross-section of operators to solicit floor input.</p>	<p>Addressed CTC-Bin mover issues by implementing a non-skid hold pad and better on/off capabilities. All capital projects on HOLD pending review.</p>	
<ul style="list-style-type: none"> <li>1. Evaluate ergonomic and safety issues associated with the Fette and CTC operations and execute action items that will result in safer procedures and fewer MLOA's.</li> </ul>				



Wyeth Ayerst Pharmaceuticals  
Train 1 2003 Performance Objectives  
Howard Henry, Production Engineer / Train 1

Compliance/Quality	Q1	Q2	Q3	Q4
<ul style="list-style-type: none"> <li>Reduce "new" Train 1 MIRs issued by 50%; (from 2002 target of NMT 32 to NMT 16) <u>WCH:</u> <u>IMR Goal</u> = NMT 75 <u>Internal Goal</u>=NMT 50. <u>Train 1:</u> <u>IMR Goal</u> = NMT 16 <u>Internal Goal</u>=NMT 10.</li> </ul>	<p>Jan: 16 Feb: 7 Mar: 24 Train 1 Average = 16 Factory Average = 71</p> <p>Team formed to evaluate root cause[s] of errors and identify trends. Leon is team leader with all Train 1 supervisors participating.</p>	<p>Apr: 14 May: 16 Jun: 20 Train 1 Average = 16.7 Factory Average = 92</p> <p>Leon and Supervisors meeting regularly and with operators to reduce errors and MIRs.</p>	<p>Jul: 24 Aug: 18 Sept: 22 Train 1 Average = 21 Factory Average = 94</p> <p>Leon and Supervisors continue to meet regularly and with operators to reduce errors and MIRs. I reviewed SOI returns to determine scope of problem and implement further corrective actions.</p>	
<ul style="list-style-type: none"> <li>Maintain NMT 3 overdue MIR's for T1. <u>WCH:</u> <u>IMR Goal:</u> NMT 13. <u>Internal Goal:</u> ZERO. <u>Train 1:</u> <u>IMR Goal:</u> NMT 3. <u>Internal Goal:</u> ZERO.</li> </ul>	<p>Factory Average = &lt;1</p>	<p>Factory Average = 2</p>	<p>Factory Average = 2</p>	
<ul style="list-style-type: none"> <li>Improve MIR 24 hour notification metric to 90%.</li> </ul>	<p>Jan: 80% Feb: 85% Mar: 62% Factory Average = 80%</p>	<p>Apr: 88% May: 90% Jun: 80% Factory Average = 86%</p>	<p>Jul: 77 Aug: 87 Sept: 88 Factory Average = 84</p>	
<ul style="list-style-type: none"> <li>Complete 100% of all Regulatory and Audit Commitments on time.</li> </ul>	<p>100% On-Time</p>	<p>100% On-Time</p>	<p>100% On-Time</p>	
<ul style="list-style-type: none"> <li>Maintain NMT zero (2)</li> </ul>	<p>Jan: 3</p>	<p>Apr: 2</p>	<p>Jul: 1</p>	



Wyeth Ayerst Pharmaceuticals  
Train 1 2003 Performance Objectives  
Howard Henry, Production Engineer / Train 1

Overdue non-Regulatory/Audit commitments.	Feb: 4 Mar: 3 Train 1 Average = 3.3	May: 5 Jun: 3 Train 1 Average = 3.3 Factory Average = 2 (SOI updates are now done quarterly, so "SOI-update" Commitments go overdue.)	Aug: 1 Sept: 1 Train 1 Average = 1 Factory Average = 1 The lone overdue was for adding "cam numbers" to the SOI. Since SOI revisions are bundled to reduce the documentation workload, this Commitment went overdue by consensus. There were several issue related to the CCP's that resulted in multiple revisions and delays	
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2566

Compliance/Quality	Q1	Q2	Q3	Q4
<ul style="list-style-type: none"> <li>Maintain zero overdue change controls.</li> </ul>	Jan: 2 Feb: 1 Mar: 0 Train 1 Average = 1	Apr: 0 May: 0 Jun: 0 Train 1 Average = 0	Jul: 0 Aug: 0 Sept: 1 Train 1 Average = 0.34	
<ul style="list-style-type: none"> <li>Achieve First Time Quality of 98% (DMR Goal).</li> </ul>	Factory Average = 98.1%	Factory Average = 97.6%	Factory Average = 99.3%	
<ul style="list-style-type: none"> <li>Achieve FTQ (internal measure) of: --Train 1: 94%</li> </ul>	Jan: 91.4% Feb: 94.8% Mar: 86.2% Average = 90.8%	Apr: 89.6% May: 89.9% Jun: 79.3% Average = 86.3%	Jul: 80.1% Aug: 90% Sept: 83.3% Train 1 Average = 85	
<ul style="list-style-type: none"> <li>Achieve Training audit pass rate of 100% (DMR)</li> </ul>	Jan: 100% Feb: 100% Mar: 100% Average = 100%	Apr: 100% May: 100% Jun: 100% Average = 100%	Jul: 100% Aug: 100% Sept: 100% Average = 100%	

Wyeth Ayerst Pharmaceuticals  
 Train 1 2003 Performance Objectives  
 Howard Henry, Production Engineer / Train 1

Customer Service	Q1	Q2	Q3	Q4
<ul style="list-style-type: none"> <li>Support lines shipped complete Goal of <u>IMR Goal</u> = 96.5% <u>Internal Goal</u> = 98%</li> <li>Achieve schedule attainment of <u>IMR Goal</u> = 85% <u>Internal Goal</u> = 98%.</li> <li>Maintain targeted finished goods DOS</li> <li>Maintain backorders at: WCH - 0, WP - 0 Bausch &amp; Lomb - 0, Int'l - LT k\$500</li> </ul>	Jan: 97.6 Feb: 99.2 Mar: 98.5 Average: 98.4%  Jan: 63% Feb: 100% Mar: 100% Average = 87.7%  Average 1-4 SKU's were below safety stock throughout the quarter.	Apr: 99.2% May: 99.0 Jun: 98.4 Average = 98.9  Apr: 100 May: 100 Jun: 100 Average = 100  SKU's below safety stock dropped to 0-1 by end of quarter.	Jul: 99.5 Aug: 99.4 Sept: 98.9 Average = 99.3  Jul: 100 Aug: 100 Sept: 100 Average = 100%  SKU's below safety stock dropped to 0-2 throughout the quarter.	
	WCH - 0 WP - k\$2,421 B & L - 40 Int'l - k\$221	WCH - 0 WP - 0 B & L - 0 Int'l - k\$16		

Wyeth Ayerst Pharmaceuticals  
 Train 1 2003 Performance Objectives  
 Howard Henry, Production Engineer / Train 1

Cost	Q1	Q2	Q3	Q4
<ul style="list-style-type: none"> <li>Maintain spending within budget excluding volume variance.</li> <li>Achieve conversion cost targets of \$6.82 WCH, \$242.81 WP</li> <li>Support inventory targets of 6.5 MOH WP and 4.5 MOH WCH</li> <li>Achieve yield targets of: Train 1 - 97%</li> </ul>	<p>Direct Labor (k\$87) favorable, other spending k\$414 unfavorable.</p> <p>1Q Average = \$8.44</p> <p>Average inventory for 1Q03 7.8 MOH WP and 5.0 MOH WCH. Increase mostly in finished goods.</p>	<p>Direct Labor (k\$447) favorable, other spending k\$684 unfavorable vs. budget despite spending k\$530 less vs. Prior year.</p> <p>2Q Average = \$7.66</p> <p>Average inventory for 2Q03 MOH 8.3 WP and 5.4 MOH WCH due to finished goods and WIP for shutdown builds.</p> <p>Train 1 A Average = 96.4% (Root cause of losses is overdosing on Fettes and dust collections. Teams in place to address both.)</p>	<p>Direct Labor (k\$765) favorable, other spending k\$1068 unfavorable vs. budget despite spending k\$975 less than 2002.</p> <p>3Q Average = \$7.91</p> <p>Average inventory for 3Q03 MOH 9.5 WP due to Mylotarg and 5.2 MOH WCH due to finished goods and WIP for shutdown builds.</p> <p>Train 1 A Average = 97%</p>	<p>Note: Sept. OT related to equipment problems and Oct. shutdown pull-up.</p>

Wyeth Ayerst Pharmaceuticals  
 Train 1 2003 Performance Objectives  
 Howard Henry, Production Engineer / Train 1

Organization	Q1	Q2	Q3	Q4
<ul style="list-style-type: none"> <li>Maintain equipment performance by executing the following tasks</li> </ul>				
1. Initiating Maximo Requests  2. Responding to off shift emergencies	1. Period: 1/1-4/30/03: 235 Requests made  2. Respond and coordinate off shift activities	1. Period: 5/1-8/28/03: 221 Requests made  2. Provided direction and guidance during the 8/18-8/22 CTC 12 batch string, contacting vendors and scheduling the cleaning and calibration of the Weigh belt in less than 10 hrs.	1. Period: 9/1-9/30/03: Requests made 68  2. Respond and coordinate off shift activities	
3. Providing off-shift coverage	3. Ongoing	3. Provided off-hour coverage during the Littleford 10K welding repair. Provide off-hour CTC coverage during equipment failures  4. Ongoing	3. Continue to respond to all emergencies handling all calls expeditiously  4. Ongoing	
4. Initiating and Closing Change Control Procedures	4. Ongoing	4. Ongoing	4. Ongoing	
5. Creating Capital Job Requisitions	5. Ongoing	5. Ongoing	5. Ongoing	
6. Sourcing new equipment	6. Ongoing. Attended Interphex. New equipment found.	6. Continue to search for new technology to replace the CTC	6. CTC Weigh belt accountability issues seemed to be	

Wyeth Ayerst Pharmaceuticals  
 Train 1 2003 Performance Objectives  
 Howard Henry, Production Engineer / Train 1

<p>7. Establish PMO timelines.</p> <p>8. Improving PMO execution by updating and improving existing PMO's.</p>	<p>Will be tested and implemented based on cost and practicality</p> <p>7. New and old equipment timelines in review</p> <p>8. Currently assisting to write and implement new CTC-PMO</p>	<p>Weigh belt and to provide de-dusting before tablets reach the unit.</p> <p>7. PMO's are assessed upon execution. Constantly improving the process with extensive scrutiny of current methods, calibration set points and checkpoints.</p> <p>8. CTC-PMO written and executed. A new change control will be written in order to tighten some parameters and to correct errors found with Thomas Engineering's method</p>	<p>resolved. Perpetual search for new technology to de-dust tablets before reaching Weigh belt.</p> <p>7. Weekly Weigh Belt calibrations appear to help maintain accountability. Will be evaluated further</p> <p>8. Currently assisting to write and implement CTC Weigh belt changes in order to improve Weigh belt performance</p>	
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New Products	Q1	Q2	Q3	Q4

Wyeth Ayerst Pharmaceuticals  
 Train 1 2003 Performance Objectives  
 Howard Henry, Production Engineer / Train 1

Special Projects	Q1	Q2	Q3	Q4
<ul style="list-style-type: none"> <li>Improve the CTC process by performing each of the following:               <ol style="list-style-type: none"> <li>Purchase new agitator shear head in order to prepare a solution in one water addition step</li> <li>Increase the dust collector fan speed to increase Weigh-belt dust removal</li> <li>Fabricate, test and purchase a dust removal system for the CTC</li> <li>Install protective plastic sheeting to prevent paint peeling in the CTC solution tank area.</li> <li>Optimizing all CTC cleaning SOP's</li> </ol> </li> </ul>	<ol style="list-style-type: none"> <li>Will be incorporated with the CTC one pass capital project.</li> <li>Change Control will be written/executed during the CTC-one pass project</li> <li>Vendors contacted Will be incorporated with the CTC-One pass project capital project</li> <li>Vendor price quote obtained. Job will be capitalized and installed during the 3<sup>rd</sup> quarter</li> <li>Ongoing</li> </ol>	<ol style="list-style-type: none"> <li>May be put on hold. SOI would have to be changed and new method would have to be validated. Not enough Tech-service staff to perform all the tasks at this time.</li> <li>Change Control will be written/executed during the CTC-one pass project</li> <li>Project ongoing. Tech service representatives currently evaluating vendors and equipment.</li> <li>Project started. The area above the tanks is complete. The other areas around the tanks will be finished during the October HVAC Shutdown.</li> <li>Ongoing. Most cleaning SOP's can remain the same. The system</li> </ol>	<ol style="list-style-type: none"> <li>Project put on hold. May be reintroduced in 1<sup>st</sup> quarter 2004</li> <li>Still part of the CTC-One Pass project activities</li> <li>Project ongoing. Tech service representatives currently evaluating vendors and equipment.</li> <li>Job will commence during the October 2003 shutdown</li> <li>Three SOP's migrated successfully into GMPharma. SOP's</li> </ol>	

Wyeth Ayerst Pharmaceuticals  
Train 1 2003 Performance Objectives  
Howard Henry, Production Engineer / Train 1

<p>6. Install platforms and ladders to provide better access to the CTC Vac-U-Max units</p> <p>• Improve 10K Littleford processing equipment</p>	<p>6. Complete</p> <p>• Redesigned Screen Shaker to prevent twist ties and other foreign objects from entering the blending process. Will be implement during the third quarter.</p>	<p>operation SOP will require minor revisions.</p> <p>6. Complete</p> <p>• Will be implemented during the HVAC equipment upgrade shutdown (October shutdown)</p>	<p>will be amended pending the results of the CTC-One Pass trial batch study</p> <p>6. Complete</p> <p>• Will be implemented during the HVAC equipment upgrade shutdown (October shutdown)</p>	
<p><b>OTHER PROJECT GOALS</b></p> <p>1. Achieve Centrum in single pass for CTC.</p>	<p>Attending Chicago rail during the week of May 5<sup>th</sup>.</p>	<p>Spectrum Spray bar system installed, tested and removed during the week of August 25<sup>th</sup> 2003. More trail optimization runs will be necessary.</p>	<p>Spectrum Spray bar spare parts identified. Will be ordered during the 4<sup>th</sup> quarter.</p>	
<p>2. Successful completion of the CTC Cleaning Qualification</p>	<p>CTC cleaning qualification complete after three successful runs on 3/8, 15 and 22. Result: No more QA verification. Equipment cleaning reduced and usage increased.</p>	<p>Complete</p>	<p>Complete</p>	
<p><b>PERSONNEL / ORGANIZATIONAL</b></p> <p>1. Maintain a personal Training TTP% of &gt;90%</p>	<p>Currently 81% as of 4/30/03</p>	<p>Currently 83% as of 8/28/03</p>	<p>Currently 84% as of 9/30/03</p>	

Wyeth Ayerst Pharmaceuticals  
Train I 2003 Performance Objectives  
Howard Henry, Production Engineer / Train I





2/11/04

Meeting of Peter Bracken

1) Reg & Mortimer

These Dks

- MADEA JOINTLY ~~PROPOSED~~ EXPERIMENTAL  
ON EXPERIMENTAL

2) No Complaintable v / Mr Going  
- Pro-Exempt. Not a Good Use  
of Resources.

3) Get Notes taken of Discussion of  
Pro.

4) Ask what I would like to do

5) Do not Read the first Appendix.

6) Retention of Assets - Mike.

7) Meeting : Discontinuation

Must be held accountable  
for what they do.

4614

**From:** Howard Henry  
**To:** Bigelow, Peter  
**Date:** 2/16/2004 10:53:53 AM  
**Subject:** Statement and Request

Good morning Pete,

After stating, during our meeting on 2/11/04, that Walter Wardrop, Andy Schaschl and Mike McDermott engaged in racial discrimination and should be held accountable for their actions, I am also stating that Joanne Rose aided in concealing this act by offering reasons to support Walter, Andy and Mike's decision to demote me to packaging instead of trying to investigate and resolve the issue.

Furthermore to date, I still have not received a copy of my changed 2003 performance evaluation. I need this document for my records should any retaliation arise, due to me proceeding with resolving this matter. Would you please contact Patti Verhasselt (x22544) so that I can obtain a copy of this performance evaluation?

Finally, thank you for stating that you did not feel comfortable with the decision to send me to packaging as a supervisor and thwarting the move to put me there.

Thanks and have a good day,  
Howard

Howard Henry  
Wyeth Pharmaceuticals  
Consumer Health Division  
40 N. Middletown Rd.  
Pearl River, NY 10965  
(845)-602-4843- Office  
(845)-602-3181-Fax



PPU	POSITION	Last Name	First Name	New Dept
	Sr. Director	Schaschl	Andrew	641
	Admin - PPU 1	Barao	Joyce	641
Centrum	Assoc Director	Espejo	Andrew	640
	Sr. Supervisor (1)	Morgan	Rich	640
	Shift Supervisor (2)	Torres	Jose	640
	Shift Supervisor (3)	Crump	Keith	640
	Vertical Cell Supvr (1)	Fleming	James	640
	Vertical Cell Supvr (2)	Vacancy		640
	Vertical Cell Supvr (3)	Rivera	Manny	640
	Production Engineer	Ordonez	Honorio	640
	Planner	Castricato	Pasqua	640
	Clerk	Gass	Alice	640
Silver	Assoc Director	Wardrop	Walter	645
	Shift Supervisor (1)	Hallock	Jennifer	645
	Shift Supervisor (2)	Hill	Vonda	645
	Shift Supervisor (3)	Abatangelo	Andrew	645
	Vertical Cell Supv (1)	Dubler	Gregory	645
	Vertical Cell Supv (2)	Damato	Michael	645
	Vertical Cell Supv (3)	Vacancy		645
	Production Engineer	Colas	Jean	645
	Planner	Edsall	Lynn	645
Packaging	Assoc Director	Bradford	Monte	735
	Packaging Supvr (1)	Yusko	Robert	735
	Packaging Supvr (1)	Henry	Howard	735
	Packaging Supvr (2)	Gaspard	Pierre	735
	Packaging Supvr (2)	Cichewicz	John	735
	Packaging Supvr (3)	Nivins	Willard	735
	Packaging Supvr (3)	Davidson	Arthur	735
	Packaging Coordinator	Szanto	Joan	735
	Sr. Packaging Engineer	Kressler	Robert	735
	Clerk	Tripp	Lauri	735
	Mgr Mfg Support	Defeciani	Chris	641
	Compliance Coord (MIR)	Deuchman	Joshua	645
	Compliance Coord (MIR)	Vacant		640

Manufacturing Support	Sr. Supvr Shop/Store Tooling	Collorafi	Michael	647
	Supvr Shop/Store Tooling	Flowers	Kenneth	647
	Sr. Prod. Engineer	Alkhawam	Aladdin	641
	Trainer	Williams	Otis	641
Not included in PPU hdct	Technical Writer	Murray	Amani	314
Not included in PPU hdct	Commitment Coord (clerk)	Washington	Gwen	310
Not included in PPU hdct	Validation (Tech dotted line)	Liu	Xiuying	602
Not included in PPU hdct	Validation (Tech dotted line)	Iqbal	Zabed	602
Not included in PPU hdct	Maint Planner (dotted line)	(Position on Maint Chart)		

<b>PPU - 2</b>	<b>POSITION</b>	<b>Last Name</b>	<b>First Name</b>	<b>New Dept</b>
	Sr. Director	Vitanza	Joseph	667
	Admin - PPU 2	Lyons	Dawn	667
	Assoc Director	Costello	Kevin	667
	Supervisor Coating (1)	Smith	Mark	648
<b>Perf/Int'l/Kids/Adults</b>	Supervisor Coating (2)	Baldi	Lou	648
<b>Fibercon/Diamox</b>	Supervisor W/B/C (1)	Couto	Paulo	648
	Sr. Supervisor Rx (1)	Shafer	William	648
	Supervisor Rx (2)	Gremli	Skip	649
	Planner Perf/Adult/Chews	Bender	Susan	667
	Planner Diamox/Fibercon	Menchini	Anne	648
	Clerk	Harrell	Brenda	667
	Dept Head	Burt	Derek	667
	Packaging Supervisor (1)	Babcock	Robert	736
<b>Packaging</b>	Packaging Supervisor (1)	Moynihan	John	737
	Packaging Supervisor (2)	Garcia	Julio	736
	Warehouse Supervisor	Natale	John	667
	Warehouse Supervisor (2)	Zayas	Excer	650
	Clerk	Short	Kathy	667
	Assoc Director	Mackey	Howard	647
	Awacs System Admin	Dyer	Kathleen	647
<b>Planning/Raws/Weigh</b>	Supervisor Weighing (2)	Lindland	Susan	647
	Supervisor Weighing (1)	Reha	Alan	647
	Planner - Raw Material	Paul	Newton	647
	Clerk	McZeek-Foster	Gwen	647
<b>Manufacturing Support</b>	Mgr Mfg Support	Muscolo	Cara	667
	Compliance Coord (MIR)	Sanford	Scott	661
	Engineer	Gloth	Jeremy	667
	Trainer	Rumpf	Gregory	667
	Engineer-Process/Water	Koziol	Jozef	667
Not included in PPU hdct	Compliance Coord (MIR)	Conace	Susan	314
Not included in PPU hdct	Technical Writer	Yang	Wei (Jessie)	314
Not included in PPU hdct	CD Remediation	Fuchs	Roger	314
Not included in PPU hdct	Validation (Technology)	Venkatesan	Sridhar	602
Not included in PPU hdct	Validation (Technology)	McGarrigle	Peter	602
Not included in PPU hdct	Maint Planner (dotted line)			



Wyeth - Pearl River

# **QUALIFICATIONS** **By Employee**

DATE 27-Feb-2004

TIME 8:54:04 AM

PAGE 1

Report emp\_qual

Course	Rev.	Description	Status	Req
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Employee: HENRY, HOWARD A

P735

Module	Rev.	Description	Status	Req
<b>Module: GMPHARMA0001 GMPharma Contributor</b>				
PPG-00000002	002	Editing Document Content	TAKEN	Y
PPG-00000003	003	Approving a Document	TAKEN	Y
PPG-00000005	002	Reviewing a Document	TAKEN	Y
PPG-00000006	002	Incorporate Review Comments Into New Draft Versions	MISSING	Y
PPG-00000007	004	GMPharma Basic Functionality	REVISION	Y
PPG-00000008	003	Document Lifecycle and Process Overview	TAKEN	Y
PPG-00000010	002	Periodic Review in GMPharma	TAKEN	Y
PPG-00000016	002	Make obsolete approval task	TAKEN	Y
PPG-00000017	002	Viewing and Searching for Documents	TAKEN	Y
PPG-00000327	002	Uncontrolled Printing	REVISION	Y
PPG-00002508	002	GMPharma EDMS Application and Use Overview	MISSING	Y

Module	Rev.	Description	Status	Req
<b>Module: GNCOM0001 RADNOR ACCENTURE COMMITMENT</b>				
COM-73	000	SOP Access in Work Areas	TAKEN	Y

Module	Rev.	Description	Status	Req
<b>Module: GNGMPA0001 CGMP ANNUAL COURSE ALL EMPLOY</b>				
COM-115	000	Adverse Experience Reporting	TAKEN	Y
GMP-19	000	2001 -ETHICAL BEHAVIOR IN OUR BUSINESS	TAKEN	Y
GMP-33	000	21 CFR Part 11: Awareness Training	TAKEN	Y
GMP-39	000	Effective, Appropriate and Compliant Communications	TAKEN	Y

Module	Rev.	Description	Status	Req
<b>Module: GNGMPA0003 CONSENT DECREE</b>				
COM-06	000	Consent Decree	TAKEN	Y

Module	Rev.	Description	Status	Req
<b>Module: GNGMPA0004 CGMP ANNUAL COURSE SUPERVISO</b>				
GMP-38	000	Driving Error Reduction	MISSING	Y

Module	Rev.	Description	Status	Req
<b>Module: GNMGTSM0001 SUPERVISORY MANAGEMENT SMDG</b>				
MGT-03	000	Communication & Listening	MISSING	Y
MGT-07	000	Performance Management (SMDG)	MISSING	Y
MGT-09	000	Safety for Supervisors (SMDG)	MISSING	Y
MGT-11	000	Leadership and Core Values	MISSING	Y
MGT-25	000	Performance Measurements and Quality	MISSING	Y
MGT-28	000	Values Workshop for Managers	MISSING	Y
MGT-29	000	Civil Treatment for Managers	MISSING	Y

Module	Rev.	Description	Status	Req
<b>Module: GNMGTSM0003 SUPERVISORY MANAGEMENT SMDG</b>				
MGT-10	000	cGMP for Supervisor/Manager - SCMD	MISSING	Y

Module	Rev.	Description	Status	Req
<b>Module: GNNEGHR0003 RESPONSIBLE COMMUNICATION ALL</b>				
SFT-22	000	SFT-22: Responsible Communications	TAKEN	Y

Module	Rev.	Description	Status	Req
<b>Module: GNSAFEM0015A SAFETY PKG. MGMT. WL V. MAN. 850.0</b>				
SAF-15	004	Evacuation and Fire Safety (OSHA)	REVISION	Y
SAF-23	004	Hand Safety	MISSING	Y

Module	Rev.	Description	Status	Req
<b>Module: GNSOPEM0001 WAP GENERAL SOP'S FOR ALL EMPL</b>				

1515





Report emp\_qual

Wyeth Pearl River

## QUALIFICATIONS

### By Employee

DATE 27-Feb-2004

TIME 8:54:04 AM

PAGE 2

Course	Rev.	Description	Status	Req
<b>Employee: HENRY, HOWARD A</b>			<b>P735</b>	
COM-126	000	Proprietary Information Protection	TAKEN	Y
PPG-00001043	004	GMP Documentation Practices - General	TAKEN	Y
PPG-00001612	003	Change Control Procedure	TAKEN	Y
PPG-00002306	001	Employee Training	TAKEN	Y
SOP20011	007	Product and Personnel Contamination Prevention	TAKEN	Y
SOP30056	006	Job Skills Training/Assessment	TAKEN	Y
SOP30112	000	Escorting Visitors at the Wyeth Pearl River, NY Site	TAKEN	Y
SOP30125	000	Security Card Reader (Badge) Access to the 100 Complex	TAKEN	Y

<b>Module: GNSOPSM0002 Div POS Core WP Global SOPs Spr/Mgr</b>				
PPG-00000588	001	Decommissioning of WAP and WLV Facilities and Equipment	TAKEN	Y
PPG-00000638	001	Contractor Management	TAKEN	Y
PPG-00000886	001	Preventative Maintenance Order (PMO) Procedure	TAKEN	Y
PPG-00000888	001	Contractor Qualification	TAKEN	Y
PPG-00000894	002	Development, Management and Control of Training Curriculum	MISSING	Y
PPG-00000907	001	Export Shipment Control to Restricted Countries	MISSING	Y
PPG-00001635	001	Pearl River Shipping Release - Preparation and Use	MISSING	Y
PPG-00001642	001	Pharmaceutical/Vaccine Compliance Program	MISSING	Y
PPG-00001723	001	Maintaining the GMP - Related Service Provider Approved List	MISSING	Y
PPG-00001860	002	Regulated Documents Processing; Including Creating, Reviewi	TAKEN	Y
PPG-00001968	001	Commitment Tracking Systems	MISSING	Y
PPG-00002066	001	Employee Locker Inspection	MISSING	Y
PPG-00005558	001	Inspection and Maintenance of Local Exhaust Hoods	MISSING	Y
SOP20046	001	Electronic Records & Signatures	MISSING	Y
SOP20195	004	Pearl River Consumer Healthcare/Pharmaceutical Quality Council	MISSING	Y
SOP30105	001	Master Equipment/Instrument List	TAKEN	Y
SOPA-039	000	Inspectional Observation Verification Process	MISSING	Y
SPIPR2K-104	003	Required OSHA Inspections	MISSING	Y

<b>Module: GNSOPSM0002A Div POS Core Read Only SOPs Spr/Mgr</b>				
POL3003	002	Absence Due to Jury Duty or Involuntary Witness Service	MISSING	Y
POL3004	002	Bereavement Leave	MISSING	Y
POL3005	003	Military Service Leave	MISSING	Y
POL3006	003	Family, Medical and Other Leaves of Absence	MISSING	Y
PPG-00001860	002	Regulated Documents Processing; Including Creating, Reviewi	TAKEN	Y
PPG-00002337	003	Trainer Qualification & Responsibilities	TAKEN	Y
SAP-PROC-008	002	SAP R/3 User Administration	MISSING	Y
SOP20001	001	Corporate Policy Document Processing	MISSING	Y
SOP20143	005	Pharmaceutical Personnel Health	TAKEN	Y
SOP20195	004	Pearl River Consumer Healthcare/Pharmaceutical Quality Council	MISSING	Y
SOP30018	001	Key Control	TAKEN	Y
SPIPR2K-101	003	Environmental, Health and Safety Policy	TAKEN	Y
SPIPR2K-105	003	Accident Investigation Procedures	MISSING	Y
SPIPR2K-201	004	Safety Work Permit Program	MISSING	Y
SPIPR2K-402	003	Hazard Communication Program	MISSING	Y
SPIPR2K-412	003	Lead Management Program	MISSING	Y
SPIPR2K-707	003	Environmental Permit/Approval Procurement Procedure	MISSING	Y
SPIPR2K-712	002	Response to Volatile Organic Compound (VOC) Leaks	MISSING	Y

<b>Module: GNSOPSM0003A Read Only SOPs Production Supervisor</b>				
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Report emp\_qual

## QUALIFICATIONS

### By Employee

DATE 27-Feb-2004

TIME 8:54:04 AM

PAGE 3

Course	Rev.	Description	Status	Req
<b>Employee: HENRY, HOWARD A</b>				
PPG-00001971	002	Qualification and Release of Critical Processing Aids, Lubri	MISSING	Y
PPG-00005683	001	Painling Procedures in Manufacturing	TAKEN	Y
<b>Module: LCH7350025 PACKAGING SUPERVISOR LCH</b>				
PPG-00000554	001	Closing Out Orders Short of FO Quantities	MISSING	Y
PPG-00000568	001	Handling and Processing a Manufacturing Investigation Report	MISSING	Y
PPG-00000610	001	Packaging Line Separation	MISSING	Y
PPG-00000868	001	Packaging Component Check-In	MISSING	Y
PPG-00000884	001	Pallet Washing Operation and Process	MISSING	Y
PPG-00001508	001	Collection of Stability Samples	MISSING	Y
PPG-00001622	001	Finishing Order (FO) Completion	MISSING	Y
PPG-00001823	002	Packaging Batch Record Specificity	MISSING	Y
PPG-00001824	001	Master Packaging Record and Packaging Batch Record	MISSING	Y
PPG-00001982	002	Generation of New and Revised Master Packaging Documents	MISSING	Y
PPG-00002060	002	Maintenance Zone Management	REVISION	Y
PPG-00002066	001	Employee Locker Inspection	MISSING	Y
PPG-00002484	001	Quality Assurance Quarantine Holds on Manufacturing Areas, E	TAKEN	Y
PPG-00008193	001	Processing a Process Order	MISSING	Y
SOP10141	007	Packaging Consumer Health Care Products (WCH)	MISSING	Y
SOP10476	001	Boekels Metal Detector (Model EMD-1518) Set-Up & Challenge	MISSING	Y
SOP10622	001	Diffuser Cleaning	MISSING	Y
SOP20284	000	Key Control for Literature Security Cages in Packaging and O	MISSING	Y
SOP20303	000	Prevention of Cross-Contamination in Corridors During Equipm	MISSING	Y
SOPB733-109	005	Line Check In	MISSING	Y
SOPB733-114	004	Preparation & Use of Non-Production Line Tria	MISSING	Y
<b>Module: LCH7350026 PACKAGING SUPERVISOR LCH</b>				
PPG-00000475	001	Set-Up and Operation Of the Lock Metal Detector and Reject M	MISSING	Y
PPG-00001588	001	Boekels Metal Detector (Model: Discovery/TI) Set-Up And Chal	MISSING	Y
PPG-00001721	001	Processing Questionable Material through Order Assembly	MISSING	Y
PPG-00001815	001	Control of Critical Packaging Supplies	MISSING	Y
PPG-00001816	001	Auxiliary Equipment Handling	MISSING	Y
PPG-00002476	001	Set-up and Operation of Calia C/R Cap Verification System	MISSING	Y
PPG-00008749	001	New England Bottle Hopper & Unscrambler (Model NEHCL)	MISSING	Y
SOP10479	001	Resina U-40 Capper Set-Up & Operation	MISSING	Y
SOP20131	004	Questionable/Unsatisfactory Components or Finished Goods	MISSING	Y
SOPM733-010	007	Packaging area Lock Up	MISSING	Y
SOPM733-016	004	Rebulk Transfer and Return Bulk	MISSING	Y
SOPM733-031	006	Work in Process Handling	MISSING	Y
<b>Module: LCH7350027 PACKAGING SUPERVISOR LCH</b>				
PPG-00000549	001	Label Key Plate Verification	MISSING	Y
PPG-00000870	001	Packaging Equipment Cleaning Facility Operation	MISSING	Y
PPG-00002040	001	Transferring Purified Water	MISSING	Y
PPG-00002285	001	Use and Maintenance of Log Books	MISSING	Y
SOP10141	007	Packaging Consumer Health Care Products (WCH)	MISSING	Y
SOP10639	000	NJM Model 311 PSR Labeler with Vision System - Set-Up and O	MISSING	Y
SOP20014	012	Packaging Audit and Destruction	MISSING	Y
SOP20028	010	Temperature and Humidity Recorder Usage	MISSING	Y
SOP20036	004	Point-Of-Use Hose (Purified Water System) Maintenance	MISSING	Y

1517



Wyeth - Pearl River

# **QUALIFICATIONS By Employee**

DATE 27-Feb-2004

TIME 8:54:04 AM

PAGE 4

Report emp\_qual

Course	Rev.	Description	Status	Req
<b>Employee: HENRY, HOWARD A</b>				
SOP20057	006	Container Monitoring	P735	
SOP20058	008	Labeler Detection System Verification	MISSING	Y
SOP20185	007	Finished Counts/Stacking Pallets	MISSING	Y
SOP20229	001	Procedure for Cleaning Mops, Buckets, Brooms and Dust Pans	MISSING	Y
SOP20265	000	Solid Dosage Bottle Packaging Line Clearance and Cleaning	MISSING	Y
SOPB733-109	005	Line Check In	MISSING	Y

Module	Rev.	Description	Status	Req
<b>Module: LCH7350028 PACKAGING SUPERVISOR LCH</b>				
PPG-00000551	001	Key Controlled Programmable and Electronic Device Security	MISSING	Y
PPG-00001002	001	Counting Boards	MISSING	Y
PPG-00001474	001	Cap Tightening and Torque Measurements	MISSING	Y
PPG-00001623	001	Completed Packaging Orders Rework	MISSING	Y
PPG-00002285	001	Use and Maintenance of Log Books	MISSING	Y
PPG-00004146	001	Sifter Loader Cleaning - Pharmaceutical Products	MISSING	Y
PPG-00004147	001	Lasko Slat Filler Cleaning - Pharmaceutical Products	MISSING	Y
PPG-00004527	001	Skill Assessment Administration for Cleaning Procedures in W	MISSING	Y
PPG-00007444	001	Packaging Product Contact Parts Cleaning Tag Usage	MISSING	Y
SOP20058	008	Labeler Detection System Verification	MISSING	Y
SOP20101	002	Sealing and Applying Shipping Carton Label to Sh	MISSING	Y
SOP20115	005	In Process Finishing Order Weekend/Holiday Shut Down	MISSING	Y
SOP20165	007	Vacuum Cleaner Use	MISSING	Y
SOP20173	007	Shortage Requisition (LPR 905) - Literature	MISSING	Y
SOPM733-064	008	Pre-making, Prelabel & On-line Coding of Shipping Cartons	MISSING	Y

Module	Rev.	Description	Status	Req
<b>Module: LCH7350037 Packaging Supervisor (Read Only)</b>				
FRM-00000235	001	Lasko Slat Filler Cleaning - Pharmaceutical Products - Check	MISSING	Y
FRM-00000236	001	Sift Loader Cleaning - Pharmaceutical Products - Checklist	MISSING	Y
PPG-00001233	002	In-Process Cleaning of Containers	MISSING	Y
PPG-00001627	001	Problem Batch Resolution Committee Charter	MISSING	Y
PPG-00002061	001	Trending of Manufacturing and Laboratory Investigations	MISSING	Y
PPG-00003047	001	Usage and Cleaning of the Packaging Line 12 Dust Containment	MISSING	Y
PPG-00004682	001	Non-Technical 21 CFR Part 11 Compliance Procedures for Pack	MISSING	Y
PPG-00005236	001	Annual Product Evaluation Reports	MISSING	Y
SOP10104	002	Merrill Filler w/ Automated Graphic Intelligent Control Syst	MISSING	Y
SOP10407	001	Callia Auto Trayer Set Up & Operation	MISSING	Y
SOP10622	001	Diffuser Cleaning	MISSING	Y
SOP20024	003	NJM 350 TSR Labeler Set-Up & Operation	MISSING	Y
SOP20036	004	Point-Of-Use Hose (Purified Water System) Maintenance	MISSING	N
SOP20097	001	Heat Induction Cap Sealers Setup & Operation	MISSING	Y
SOP20272	002	Ideal Bundler & Pack-All Heat Tunnel Setup and Operation	MISSING	N
SOPA-007	008	Converted to PPG-00005236 Annual Product Evaluation	MISSING	Y

Module	Rev.	Description	Status	Req
<b>Module: LCHSUP0003 LCH SUP MANUFACTURING SUPPORT</b>				
PPG-00000409	001	Execution of Cleaning Validation Protocols	MISSING	Y
PPG-00000439	001	Execution of a Process Validation Protocol for Marketed Drug	MISSING	Y
PPG-00000440	003	Preparation and Execution of Study Plans and Investigations	MISSING	Y
PPG-00000635	001	Investigation - Root Cause Analysis	TAKEN	Y
PPG-00000706	001	Retrospective Validation of Existing Products - Pharmaceutical	MISSING	Y
PPG-00001138	001	Sampling Validation Batches	MISSING	Y
PPG-00001609	002	Initiation & Completion of Pilot Batches	REVISION	Y

1518



Report emp\_qual

# **QUALIFICATIONS** **By Employee**

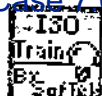
DATE 27-Feb-2004

TIME 8:54:04 AM

PAGE 5

Course	Rev.	Description	Status	Req
<b>Employee: HENRY, HOWARD A</b>				
			<b>P735</b>	
PPG-00002059	002	Equipment/Room Hold Time	TAKEN	Y
PPG-00002677	003	Manufacturing Equipment/Production Room Cleaning and Use	MISSING	Y
PPG-00008619	001	Manufacturing Equipment Cleaning and Use of Cleaning Checkli	MISSING	Y
SOP10445	001	Investigation of Failed Cleaning Validation	MISSING	Y
SOP10446	002	Protocol Preparation for Periodic Re-Qualification of Equip	MISSING	Y
SOP10447	002	Protocol Preparation for Existing Equipment Qualification	MISSING	Y
SOP10448	002	Execution of New Equipment Qualification	MISSING	Y
SOP10449	002	Final Report Preparation for Equipment Qualification	MISSING	Y
SOP10450	002	Protocol Preparation for New Equipment Qualification	MISSING	Y
SOP10451	002	Final Report Preparation for Period Equipment Re-Qualificati	MISSING	Y
SOP10452	002	Execution of Period Equipment Re-Qualification	MISSING	Y
SOP20135	003	Cleaning Between Product String Guideline - Manufacturing/Pa	REVISION	Y
SOP30122	000	Distribution and Use of Daily Access Badges in the 100 Compl	TAKEN	Y
SOPP-010	002	The Pilot Batch	REVISION	Y
<b>Module: PC12360011 TRAINER QUALIFICATION FOR CLASS</b>				
COM-08	000	Trainer Qualifications for SOP & GMP	TAKEN	Y
PPG-00002306	001	Employee Training	TAKEN	Y
PPG-00002337	003	Trainer Qualification & Responsibilities	TAKEN	Y
<b>Module: PC12360012 EOJT QUALIFICATION ON THE JOB TR</b>				
EOJT001	000	EOJT Trainer Qualification Program - 1/2 Day	TAKEN	Y
PPG-00002337	003	Trainer Qualification & Responsibilities	TAKEN	Y
SOP30056	006	Job Skills Training/Assessment	TAKEN	Y
<b>Module: PC12360018 Regulated Documents Access and Proce</b>				
PPG-00001860	002	Regulated Documents Processing; Including Creating, Reviewi	TAKEN	Y
<b>Module: PC12360021 IsoTrain Viewer</b>				
IS-02	000	ISOtrain "View Only" Access Review - Specialized 2001	MISSING	Y
PPG-00002085	002	ISOtrain System Use Overview and Documentation Responsibility	MISSING	Y
<b>Module: SAPMRP0001 Basic Navigation</b>				
PPG-00004121	001	Key Terms in SAP	MISSING	Y
SAP-BN	003	SAP Basic Navigation	MISSING	Y
<b>Module: SAPMRP0032 Process Confirmation Order</b>				
SAP-POCPR	001	PP: Process Orders Confirmations for Pearl River	MISSING	Y
<b>Module: SAPMRP0046 Transfer Posting</b>				
SAP-TPOSTPR	001	WM: Transfer Posting for Pearl River	MISSING	Y
<b>Module: SAPMRP0052 NovaManage BOM</b>				
PPG-00004794	001	Obtain, Verify and Complete the Nova Manage Bill of Material	MISSING	Y
<b>Module: SAPOVR0002 SAP Overviews - Warehouse Only</b>				
SAP-WMOPR	001	WM: Warehouse Management Overview for Pearl River	MISSING	Y
<b>Module: SAPOVR0013 Process Order Overview</b>				





Wyeth - Pearl River

## QUALIFICATIONS

By Employee

DATE 27-Feb-2004

TIME 8:54:04 AM

PAGE 6

Report emp\_qual

Course	Rev.	Description	Status	Req
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Employee: HENRY, HOWARD A

SAP-POOPR

001 Process Orders Overview for Pearl River

P735

MISSING

Y

Module: WCH7380003 Supervisor (Read Only - ESI Only)

PPG-00000436	001	Omega Bottle Unscrambler Set-Up	MISSING	Y
PPG-00000689	001	Set-Up and Operation of New Jersey Machine Circular Applicat	MISSING	Y
PPG-00001007	001	Set-Up and Operation of CT Code Line 9 Circular Verification	MISSING	Y
PPG-00001032	001	Lakso 900 Filler and Sifty Loader Set-Up and Operation	MISSING	Y
PPG-00001351	001	Thermocode 5775 Printer Set-Up/Operation	MISSING	Y
PPG-00004146	001	Sifter Loader Cleaning - Pharmaceutical Products	MISSING	Y
PPG-00004147	001	Lasko Slat Filler Cleaning - Pharmaceutical Products	MISSING	Y
SOP10165	003	Portable CT Code System Set-Up and Operation	MISSING	Y
SOP10330	003	Omega Bottle Unscrambler Operation	MISSING	Y
SOP10481	000	Pace Pharma-Line Model 300 Bottle Hopper & Unscrambler Set-	MISSING	Y

Module: WPGATW0003 TrackWise Commitment User Training

PPG-00000482	001	Overview of the TrackWise Event Reporting and Tracking Syste	MISSING	Y
PPG-00000609	001	Commitment Initiation and Tracking Using the TrackWise Data	TAKEN	Y
PPG-00001968	001	Commitment Tracking Systems	MISSING	Y
SOP20075	011	Manufacturing Investigation Report (MIR) System	TAKEN	Y

Module: WPGATW0004 TrackWise MIR-ERF User Training

COM-02	000	Investigation Training - Module 2, Situation Review	MISSING	Y
COM-03	000	Investigation Training - Module 3, Cause Analysis	MISSING	Y
IS-57	000	Track Wise Introduction	TAKEN	Y
PPG-00000482	001	Overview of the TrackWise Event Reporting and Tracking Syste	MISSING	Y
PPG-00000568	001	Handling and Processing a Manufacturing Investigation Report	MISSING	Y
SOP20075	011	Manufacturing Investigation Report (MIR) System	TAKEN	Y

Total Courses: 211

Taken: 49

Missing: 155

Revision: 7

Qual%: 23.22

\*\*\* End of Report \*\*\*



Report ITP\_EMP

Wyeth - Pearl River

# % CURRENT EMPLOYEES IN ITP REPORT BY EMPLOYEE

DATE 27-Feb-2004

TIME 8:55:54 AM

PAGE 1

NAME	REQ.	COMPL. ITP	DUE ITP	% CURR.ITP
DEPARTMENT: LP735				
CHP PACKAGING				
HENRY, HOWARD A	209	51	158	24%
<u>TOTAL DEPARTMENT</u>	209	51	158	24%

\*\*\* End of Report \*\*\*



Wyeth - Pearl River

# Employee Catalog

## By Profession

DATE 01-Mar-2004

TIME 10:26:45 AM

PAGE 1

Report PROF\_EMP

Name	Status	Type	Class	Dept
<b>Profession: ADM COORD</b>				
TRIPP, LAURI J	A	A	W	P735
<b>Total Profession: 1</b>				
<b>Profession: ASC DIR PKG</b>				
BRADFORD, MONTE W	A	A	S	P735
<b>Total Profession: 1</b>				
<b>Profession: FLOOR LDR PKG</b>				
BROWN, ELNORA	A	A	H	P735
BULLOCK, JESSIE L	A	A	H	P735
SCHULTZ, ELLEN V	A	A	H	P735
<b>Total Profession: 3</b>				
<b>Profession: PKG COORD</b>				
SZANTO, JOAN M	A	A	S	P735
<b>Total Profession: 1</b>				
<b>Profession: PKG LINE MECH S/B 4</b>				
AGOLIA, MICHAEL W	A	A	H	P735
BLAUVELT, THOMAS A	A	A	H	P735
BROADHEAD, DAVID O	A	A	H	P735
EUSTACE, ROBERT P	A	A	H	P735
FUHRMANN, BRUCE W	A	A	H	P735
MILLER, JEFFREY J	A	A	H	P735
OSTROWSKI, PETER J	A	A	H	P735
RENELLA, MICHAEL W	A	A	H	P735
RIVERS JR, EARNEST S	A	A	H	P735
ROBERTS, HUBERT F	A	A	H	P735
WOODMANSEE, WARREN W	A	A	H	P735
<b>Total Profession: 11</b>				
<b>Profession: PKG OPER S/B 1</b>				
KOWALSKI, JASON W	A	A	H	P735
LA POLLA, JIM V	A	A	H	P735
MC CORKLE, PATRICE S	A	A	H	P735
<b>Total Profession: 3</b>				
<b>Profession: PKG OPER S/B 2</b>				
BLEDSON, OLGA I	A	A	H	P735
BOROVCANIN, ZORAN	A	A	H	P735
CICERON, RONARCK	A	A	H	P735
DAVIS, PIERRE A	A	A	H	P735
JOHNSON, GARY J	A	A	H	P735
MENNELL, CHERYL A	A	A	H	P735
PATEL, INDRAVADAN K	A	A	H	P735
RIVAS, NELSON	A	A	H	P735
STAWSKI, JOHN R	A	A	H	P735
WILLIAMS, LEONA M	A	A	H	P735
<b>Total Profession: 10</b>				



Wyeth - Pearl River

## Employee Catalog

By Profession

DATE 01-Mar-2004

TIME 10:26:45 AM

PAGE 2

Report PROF\_EMP

Name	Status	Type	Class	Dept
<b>Profession: PKG OPER S/B 3</b>				
CHINDEMI, GREGORY P	A	A	H	P735
FIERSTEIN, IRA L	A	A	H	P735
MICKLE, GERRY	A	A	H	P735
<b>Total Profession: 3</b>				
<b>Profession: PKG OPER S/B 4</b>				
BIBBINS, CHERYL L	A	A	H	P735
BRANCH, SHERRY K	A	A	H	P735
BREVAL, JEAN Y	A	A	H	P735
BURNS, SHARON L	A	A	H	P735
CHATELAIN, JEAN C	A	A	H	P735
CLARK, ANNETTE L	A	A	H	P735
DIAZ, RAFAEL	A	A	H	P735
DIAZ, RAFAEL A	A	A	H	P735
DUMEL, JACQUELIN	A	A	H	P735
DYKSTRA, DOROTHY	A	A	H	P735
ELOI, ANDREE R	A	A	H	P735
ESPINAL, LIGIA M	A	A	H	P735
EVANS, JR., CLARENCE E	A	A	H	P735
FELTS, CHESTER L	A	A	H	P735
FLYNN, MICHAEL G	A	A	H	P735
FRANCIS, FRITZROY N	A	A	H	P735
GASS, KELLY A	A	A	H	P735
GASS, NICOLE L	A	A	H	P735
GILET, YVES L	A	A	H	P735
GORHAM, MABLE	A	A	H	P735
HARRIS, GEORGE P	A	A	H	P735
HARRIS, SERENA M	A	A	H	P735
HERBERT, DASSY M	A	A	H	P735
JEAN-CHARLES, CLOSETTE	A	A	H	P735
JEAN-CHARLES, ROMAIN	A	A	H	P735
LEONARD, JACQUELYN	A	A	H	P735
LESCOUFLAIR, RACHELLE	A	A	H	P735
MARTUCCI, MARIO M	A	A	H	P735
MARTUCCI, PATRICIA A	A	A	H	P735
MCINTIRE, BRUCE E	A	A	H	P735
MOTT, BARRY M	A	A	H	P735
MURPHY, PATRICK D	A	A	H	P735
MYERS, PATRICK D	A	A	H	P735
NENNA, RICHARD T	A	A	H	P735
OSIAS-JAMES, RACHEL I	A	A	H	P735
PARRIS, SIDNEY W	A	A	H	P735
PEREZ, OSCAR M	A	A	H	P735
PERSONEUS, BRUCE G	A	A	H	P735
POOLE, NENAH M	A	A	H	P735
QUINN JR, JOSEPH P	A	A	H	P735
REID, ARVINESE I	A	A	H	P735
RIZZETTA, DEBORAH T	A	A	H	P735
ROBERTS, MICHELLE A	A	A	H	P735



Wyeth - Pearl River

Report PROF\_EMP

# Employee Catalog

## By Profession

DATE 01-Mar-2004

TIME 10:26:45 AM

PAGE 3

Name	Status	Type	Class	Dept
ROSARION, YOLANDE M	A	A	H	P735
ROTH, RICHARD H	A	A	H	P735
RUBIO, OLGA	A	A	H	P735
RUIZ QUINONEZ, LOURDES M	A	A	H	P735
RYAN, THOMAS J	A	A	H	P735
SAHADITGUL, PRICHA	A	A	H	P735
SAINT CYR, MYRIAM M	A	A	H	P735
SCELFO, ANTONINO	A	A	H	P735
SCOTT, BESSIE M	A	A	H	P735
SCOTT, ELLEN A	A	A	H	P735
SMITH, MICHELLE R	A	A	H	P735
STRASSBURG, JEANETTE C	A	A	H	P735
STREET, WILLIAM K	A	A	H	P735
SYLVESTER, ANNIE	A	A	H	P735
TAIANI, MICHAEL	A	A	H	P735
TERMORA, JEAN	A	A	H	P735
THOMAS, EDNA M	A	A	H	P735
THOMPSON, BRENDA J	A	A	H	P735
VETTER, DIANE M	A	A	H	P735
WELLINGTON, ORTEZ D	A	A	H	P735
ZAMOR, PAUL	A	A	H	P735
ZUCATTI, MARIA	A	A	H	P735
<b>Total Profession:</b> 65				
<b>Profession: PKG SPVR</b>				
CICHEWICZ, JOHN J	A	A	S	P735
DAVIDSON, ARTHUR J	A	A	S	P735
GASPARD, PIERRE D	A	A	S	P735
NIVINS, WILLARD M	A	A	S	P735
<b>Total Profession:</b> 4				
<b>Profession: SPVR PKG</b>				
HENRY, HOWARD A	A	A	S	P735
YUSKO, ROBERT V	A	A	S	P735
<b>Total Profession:</b> 2				
<b>Profession: SR PKG ENGR</b>				
KRESSLER, ROBERT P	A	A	S	P735
<b>Total Profession:</b> 1				
<b>Profession: TEMP SPVR HRLY</b>				
JONES, KAREN A	A	A	H	P735
<b>Total Profession:</b> 1				

\*\*\* End of Report \*\*\*





Wyeth - Pearl River

## MODULES BY EMPLOYEE

DATE 01-Mar-2004

TIME 10:29:56 AM

PAGE 1

Report MOD\_EMP

NAME	MODULE DATE	
	FROM	TO
Module: GNSQPSM0003A Read Only SOPs Production Supervisor/Manager		
ABATANGELO, ANDREW G	14-Aug-1989	
BALDI SR, LOUIS A	29-Nov-1976	
BURT, DEREK H	16-Nov-1999	
COSTELLO JR, KEVIN M	08-Jun-1992	
COUTO, PAULO M	01-Apr-2002	
CRUMP, KEITH B	09-Jul-1990	
DAMATO, MICHAEL J	21-Oct-2002	
DUBLER, GREGORY F	24-Feb-2003	
DYER, KATHLEEN D	03-Mar-2003	
ESPEJO, ANDREW S	24-Apr-2001	
FLEMING, JAMES F	08-Sep-1997	
FLOWERS, KENNETH C	28-Apr-1980	
GASPARD, PIERRE D	16-Jul-1984	
GIBSON, JAMES M	23-Oct-1980	
HALLOCK, JENNIFER R	10-Jul-2001	
HENRY, HOWARD A	09-Aug-1993	
HILL, VONDA L	02-Dec-1985	
LINDLAND, SUSAN G	05-Oct-1999	
MORGAN, RICHARD C	03-Feb-1986	
MOYNIHAN, JOHN J	28-Sep-1977	
NATALE, JOHN	04-May-1970	
NIVINS, WILLARD M	04-Sep-1990	
REHA, ALAN R	17-Oct-1983	
RIVERA, MANUEL P	29-Sep-2003	
SANCHEZ JR, MANUEL	24-Jun-2002	
SCHASCHL, ANDREW N	01-Oct-1984	
SHAFFER JR, WILLIAM E	26-Jun-2001	
SNELL, CHRISTOPHER G	19-Jan-2004	
WARDROP, WALTER J	25-Apr-1977	
YUSKO, ROBERT V	19-Mar-1984	
ZAYAS, EXCER R	16-Sep-1985	

**Total Employees: 31****Total all Employees: 31**



Wyeth - Pearl River

**MODULES BY EMPLOYEE**

DATE 01-Mar-2004

TIME 10:30:29 AM

PAGE 1 -

Report MOD EMP

NAME	----MODULE DATE----	
	FROM	TO
Module: LCHPRODENG0001 - ALL LCH PROD ENGINEERS		
COLAS, JEAN	01-Jan-1990	
ORDONEZ, HONORIO L	16-Jun-2003	
<b>Total Employees: 2</b>		

**Total all Employees: 2**



Wyeth - Pearl River

## MODULES BY EMPLOYEE

DATE 01-Mar-2004

TIME 10:31:01 AM

PAGE 1

Report MOD EMP

NAME	-----MODULE DATE-----
	FROM TO
Module: CH7350056 Senior Packaging Engineer (Read Only)	
KRESSLER, ROBERT P	01-Jan-1990
<u>Total Employees:</u> 1	

Total all Employees: 1

List Edit Goto System Help

Function



## Employee Data Verification Report

ZTER\_EMPDATA  
P01 - 400  
HENRYH

Wyeth Pharmaceuticals  
Employee Data Verification Report

Page: 1  
Date: 03/17/2004  
Time: 10:33:23

Please review this data before entering expenses

Name: HOWARD HENRY  
Cost Center: 1061735 LCH PACKAGING  
Last 4 digits of SSN: 2014

Reports to (Approver): MONTE BRADFORD

[REDACTED]

**From:** Howard Henry  
**To:** Burt, Derek  
**Date:** 1/30/2004 8:44:39 AM  
**Subject:** Training Sessions

Good morning Derek,

I was made aware that during yesterday's SAP training session, the instructor called my name while checking attendance. However, it was never communicated to me that I should attend the session or any subsequent SAP sessions.

I was told to function and perform duties in my current position until further notice. Please let me know if you have other information or have been communicated something contrary.

Thanks,  
Howard

**From:** Derek Burt  
**To:** Henry, Howard  
**Date:** 2/2/2004 10:31:29 AM  
**Subject:** SAP Training

Howard,  
Sorry for the delay, but as you know the end of the month brings Attainment and there were a lot of other issues and priorities to fit into my schedule.  
That said, I requested that your name be removed from the SAP training schedule. I understand that you will no longer require this training as you are to resume your duties as Manufacturing Engineer.  
If you have any questions, please call me.

Derek

**CC:** Wardrop, Walter

**From:** "WORKFLOW SYSTEM" <SAP-Workflow@wyeth.com>  
**To:** <HENRYH@wyeth.com>  
**Date:** 3/19/2004 3:16:02 PM  
**Subject:** Expense Report Approved 1600026587

Dear Employee,

Your expense report 1600026587 has been approved by your manager.

Please be sure to place your receipts in a Travel & Entertainment envelope, write your name and trip number on the envelope and forward to Travel and Entertainment.

- T&E Administrator

**Trip Details**

**Date :** 03/16/2004 - 03/16/2004

**Reason :** Interphex 2004

This is a system generated message. Please do not attempt to reply.

**Expense Report Summary**

<b>Employee Name:</b>	HOWARD HENRY	<b>Trip Number:</b>	1600026587
<b>Date :</b>	03/16/2004 - 03/16/2004		
<b>Reason :</b>	Interphex 2004	<b>Expenses in USD</b>	<b>Visa:</b> 39.35
<b>Location :</b>	New York, NY		<b>Employee:</b> 23.26
<b>Country :</b>	US		<b>Total:</b> 62.61

**Mileage Expense**

Date	Type	No. Miles	Company Amount	Amount in USD
03/16/2004	Pers Car	31	0.37500	11.63 <a href="#">Details</a>
03/16/2004	Pers Car	31	0.37500	11.63 <a href="#">Details</a>
<b>Total Mileage in USD</b>				23.26

**Individual Receipt Reimbursement**

Date	Receipt No	Receipt Type	Receipt Description	Amount in USD
03/16/2004	001	Lunch Self		10.35
03/16/2004	002	Parking / Tolls		29.00 <a href="#">Details</a>
<b>Total Receipt in USD</b>				39.35

**Total Expenses to be charged as follows:**

Company Code	Cost Center	Order No	WBS	Amount in USD USD
16	1061735			62.61
				62.61

Good Morning Monte,

Andrew Espejo told me he would speak to you about approving this expense report because an EAN would have to be initiated in order to change him to be the approving manager.

Please contact me if you have any questions.

Thank you,

Howard Henry



Back Print

**Megan Arzberger****Travel Expense Report**

From: John Cancellieri (JohnCinNH@CinNH.com)

Sent: Wednesday, April 19, 2006 7:55 PM

Employee Name: Megan Arzberger

Trip Number: 1600026587

Subject: Investigators  
Date: 03/16/2004 - 03/16/2004

Reason: Interphex 2004

Expenses in USD Visa: 39.35

Location: New York, NY

Employee: 23.26

Country: US

Total: 62.61

4 Gasco Drive Apt # 8  
Nashua, NH 03062  
603-765-2685**Mileage Expense**

Lead investigator for NH. I obtained my NH license through him. He left as lead investigator in December because he got a job as a correctional officer. He was upset over the lack of business and false promises. He met with Ed in the Mass. office

Date	Type	No. Miles	Company Amount	Amount in USD
03/16/2004	Pers Car	31	0.37500	11.63

Start Location: Hillcrest, NY

Topsham, ME 04086

End Location: New York, NY

He said I could work under his Maine license. He did so with the understanding I would give him business. I never did. He never spoke with L & W, but did speak with Ed on phone.

Start Location: New York, NY

End Location: Hillcrest, NY

**Total Mileage in USD**

23.26

**Individual Receipt Reimbursement**

Date	Receipt No.	Receipt Type	Amount in USD
03/16/2004	001	Lunch Self	10.35
03/16/2004	002	Parking / Tolls	29.00

Parking Fees: \$25.00

George Washington Bridge: \$4.00

**Total receipt in USD**

39.35

**Total Expenses to be charged as follows:**

Company Code Cost Center Order No.

WBS

Amount in USD

16 1061735

62.61

1501

62.61

Good Morning Monte

4/20/2006

André y Espejo told me he would speak to you about approving this expense report because an EAN would have to be initiated in order to change him to be the approving manager.

Please contact me if you have any questions.

Thank you.

Howard Henry

[Back](#)

[Print](#)

Ninth Avenue Parking LIC #1142024  
404 West 37th St., 212-629-6397  
Ticket: 7304 (70-6179) Veh: NY-BCP5834  
Type: Transient Cashier: OSCAR  
Printed: 3/16/2004 12:16 PM

JAVITZ RATE	\$ 25.00
FROM 3/16/2004 11:29:00 AM	
TO 3/16/2004 12:45:00 PM	
Gross Charge	\$ 25.00
(0d-1h-16m) PARKING CHARGES	\$ 25.00
SERVICE CHARGES	\$ 0.00
TOTAL CHARGES	\$ 25.00
ADJUST & PREV PNTS	\$ 0.00
BALANCE DUE:	\$ 25.00
3/16/2004 12:16 PM OSCAR 70 Visa	\$ 25.00
Card: 4512 Exp: 0106 Auth: 090370	
BALANCE DUE:	\$ 0.00

Thank You. Come Again

Customer Copy

FOOD HUT CARIBBEAN  
CUISINE  
1709 AMSTERDAM AVENUE  
NEW YORK, NY 10031  
(212) 491-4492

C O P Y  
03/16/2004 01:44  
Sale:

Transaction # 1  
Card Type: VISA  
Acc: \*\*\*\*\*4512  
Entry: Swiped  
Total: 10.35

Reference No.: 946229195  
Auth. Code: 022595  
Respon. APPROVAL 022595

**MISSING REQUIREMENTS****By Employee**

DATE 27-Feb-2004

TIME 8:54:56 AM

PAGE 1

Report MISSEM

Name

Department/

Eff. Date

Status

Req.

HENRY, HOWARD A

P735

COM-02	000	Investigation Training - Module 2, Situation Review		MISSING	Y
COM-03	000	Investigation Training - Module 3, Cause Analysis		MISSING	Y
FRM-00000235	001	Lasko Slat Filler Cleaning - Pharmaceutical Products - Check	31-Oct-2003	MISSING	Y
FRM-00000236	001	Sifty Loader Cleaning - Pharmaceutical Products - Checklist	31-Oct-2003	MISSING	Y
GMP-38	000	Driving Error Reduction		MISSING	Y
IS-02	000	ISOtrain "View Only" Access Review - Specialized	24-Aug-2000	MISSING	Y
		2001			
MGT-03	000	Communication & Listening		MISSING	Y
MGT-07	000	Performance Management (SMDC)		MISSING	Y
MGT-09	000	Safety for Supervisors (SMDC)		MISSING	Y
MGT-10	000	cGMP for Supervisor/Manager - SCMD		MISSING	Y
MGT-11	000	Leadership and Core Values		MISSING	Y
MGT-25	000	Performance Measurements and Quality		MISSING	Y
MGT-28	000	Values Workshop for Managers	24-Jun-2002	MISSING	Y
MGT-29	000	Civil Treatment for Managers	24-Jun-2002	MISSING	Y
POL3003	002	Absence Due to Jury Duty or Involuntary Witness Service	01-Jul-2002	MISSING	Y
POL3004	002	Bereavement Leave	01-Jul-2002	MISSING	Y
POL3005	003	Military Service Leave	28-Apr-2003	MISSING	Y
POL3006	003	Family, Medical and Other Leaves of Absence	27-Mar-2003	MISSING	Y
PPG-00000006	002	Incorporate Review Comments Into New Draft Versions	16-Sep-2002	MISSING	Y
PPG-00000007	004	GMPharma Basic Functionality	10-Nov-2003	REVISION	Y
PPG-00000327	002	Uncontrolled Printing	10-Nov-2003	REVISION	Y
PPG-00000409	001	Execution of Cleaning Validation Protocols	07-Jul-2003	MISSING	Y
PPG-00000436	001	Omega Bottle Unscrambler Set-Up	04-Jun-2003	MISSING	Y
PPG-00000439	001	Execution of a Process Validation Protocol for Marketed Drug	30-Jun-2003	MISSING	Y
PPG-00000440	003	Preparation and Execution of Study Plans and Investigations	22-Dec-2003	MISSING	Y
PPG-00000475	001	Set-Up and Operation Of the Lock Metal Detector and Reject M	04-Jun-2003	MISSING	Y
PPG-00000482	001	Overview of the TrackWise Event Reporting and Tracking Syste	30-Jul-2003	MISSING	Y
PPG-00000549	001	Label Key Plate Verification	09-Jun-2003	MISSING	Y
PPG-00000551	001	Key Controlled Programmable and Electronic Device Security	01-Aug-2003	MISSING	Y
PPG-00000554	001	Closing Out Orders Short of FO Quantities	01-Aug-2003	MISSING	Y
PPG-00000568	001	Handling and Processing a Manufacturing Investigation Report	04-Feb-2003	MISSING	Y
PPG-00000610	001	Packaging Line Separation	05-Jun-2003	MISSING	Y
PPG-00000689	001	Set-Up and Operation of New Jersey Machine Circular Applicat	11-Jul-2003	MISSING	Y
PPG-00000706	001	Retrospective Validation of Existing Products - Pharmaceutic	24-Jun-2003	MISSING	Y
PPG-00000868	001	Packaging Component Check-In	04-Jun-2003	MISSING	Y
PPG-00000870	001	Packaging Equipment Cleaning Facility Operation	04-Jun-2003	MISSING	Y
PPG-00000884	001	Pallet Washing Operation and Process	31-Oct-2003	MISSING	Y

1464



# MISSING REQUIREMENTS By Employee

DATE 27-Feb-2004

TIME 8:54:56 AM

PAGE 2

Report MISSEM

Name			Department/ Eff. Date	Status	Req.
PPG-00000894	002	Development, Management and Control of Training Curriculum	28-Oct-2003	MISSING	Y
PPG-00000907	001	Export Shipment Control to Restricted Countries	04-Feb-2003	MISSING	Y
PPG-00001002	001	Counting Boards	14-Apr-2003	MISSING	Y
PPG-00001007	001	Set-Up and Operation of CT Code Line 9 Circular Verification	14-Apr-2003	MISSING	Y
PPG-00001032	001	Lakso 900 Filler and Sifty Loader Set-Up and Operation	05-Jun-2003	MISSING	Y
PPG-00001138	001	Sampling Validation Batches	16-Apr-2003	MISSING	Y
PPG-00001233	002	In-Process Cleaning of Containers	31-Oct-2003	MISSING	Y
PPG-00001351	001	Thermocode 5775 Printer Set-Up/Operation	20-Jun-2003	MISSING	Y
PPG-00001474	001	Cap Tightening and Torque Measurements	04-Apr-2003	MISSING	Y
PPG-00001508	001	Collection of Stability Samples	04-Apr-2003	MISSING	Y
PPG-00001588	001	Boekels Metal Detector (Model: Discovery/TI) Set-Up And Chal	20-Jun-2003	MISSING	Y
PPG-00001609	002	Initiation & Completion of Pilot Batches	22-Sep-2003	REVISION	Y
PPG-00001622	001	Finishing Order (FO) Completion	04-Apr-2003	MISSING	Y
PPG-00001623	001	Completed Packaging Orders Rework	03-Apr-2003	MISSING	Y
PPG-00001627	001	Problem Batch Resolution Committee Charter	13-Oct-2003	MISSING	Y
PPG-00001635	001	Pearl River Shipping Release - Preparation and Use	04-Feb-2003	MISSING	Y
PPG-00001642	001	Pharmaceutical/Vaccine Compliance Program	12-Feb-2003	MISSING	Y
PPG-00001721	001	Processing Questionable Material through Order Assembly	30-Jun-2003	MISSING	Y
PPG-00001723	001	Maintaining the GMP - Related Service Provider Approved List	14-Nov-2003	MISSING	Y
PPG-00001815	001	Control of Critical Packaging Supplies	15-Aug-2003	MISSING	Y
PPG-00001816	001	Auxiliary Equipment Handling	03-Apr-2003	MISSING	Y
PPG-00001823	002	Packaging Batch Record Specificity	11-Dec-2003	MISSING	Y
PPG-00001824	001	Master Packaging Record and Packaging Batch Record	10-Nov-2003	MISSING	Y
PPG-00001968	001	Commitment Tracking Systems	07-May-2003	MISSING	Y
PPG-00001971	002	Qualification and Release of Critical Processing Aids, Lubri	12-Nov-2003	MISSING	Y
PPG-00001982	002	Generation of New and Revised Master Packaging Documents	21-Nov-2003	MISSING	Y
PPG-00002040	001	Transferring Purified Water	08-Jul-2003	MISSING	Y
PPG-00002060	002	Maintenance Zone Management	30-Jun-2003	REVISION	Y
PPG-00002061	001	Trending of Manufacturing and Laboratory Investigations	07-Feb-2003	MISSING	Y
PPG-00002066	001	Employee Locker Inspection	07-Feb-2003	MISSING	Y
PPG-00002085	002	ISOTrain System Use Overview and Documentation Responsibility	12-Feb-2004	MISSING	Y
PPG-00002285	001	Use and Maintenance of Log Books	23-Jun-2003	MISSING	Y
PPG-00002476	001	Set-up and Operation of Calla C/R Cap Verification System	23-Jun-2003	MISSING	Y
PPG-00002508	002	GMPharma EDMS Application and Use Overview	31-Dec-2003	MISSING	Y
PPG-00002677	003	Manufacturing Equipment/Production Room Cleaning and Use of	31-Oct-2003	MISSING	Y
PPG-00003047	001	Usage and Cleaning of the Packaging Line 12 Dust Containment	14-Aug-2003	MISSING	Y
PPG-00004121	001	Key Terms in SAP	15-Sep-2003	MISSING	Y
PPG-00004146	001	Sifter Loader Cleaning - Pharmaceutical Products	31-Oct-2003	MISSING	Y





## MISSING REQUIREMENTS

### By Employee

DATE 27-Feb-2004

TIME 8:54:56 AM

PAGE 3

Report MISSEM

Name			Department/ Eff. Date	Status	Req.
PPG-00004147	001	Lasko Slat Filler Cleaning - Pharmaceutical Products	31-Oct-2003	MISSING	Y
PPG-00004527	001	Skill Assessment Administration for Cleaning Procedures in W	16-Jul-2003	MISSING	Y
PPG-00004682	001	Non-Technical 21 CFR Part 11 Compliance Procedures for Packa	30-Jun-2003	MISSING	Y
PPG-00004794	001	Obtain, Verify and Complete the Nova Manage Bill of Material	01-Nov-2003	MISSING	Y
PPG-00005236	001	Annual Product Evaluation Reports	16-Dec-2003	MISSING	Y
PPG-00005558	001	Inspection and Maintenance of Local Exhaust Hoods	15-Sep-2003	MISSING	Y
PPG-00007444	001	Packaging Product Contact Parts Cleaning Tag Usage	31-Oct-2003	MISSING	Y
PPG-00008193	001	Processing a Process Order	29-Jan-2004	MISSING	Y
PPG-00008619	001	Manufacturing Equipment Cleaning and Use of Cleaning Checkli	10-Mar-2004	MISSING	Y
PPG-00008749	001	New England Bottle Hopper & Unscrambler (Model NEHCL)	13-Feb-2004	MISSING	Y
SAF-15	004	Evacuation and Fire Safety (OSHA)	01-Jan-2004	REVISION	Y
SAF-23	004	Hand Safety	01-Jan-2004	MISSING	Y
SAP-BN	003	SAP Basic Navigation	15-Sep-2003	MISSING	Y
SAP-POCPR	001	PP: Process Orders Confirmations for Pearl River	20-Oct-2003	MISSING	Y
SAP-POOPR	001	Process Orders Overview for Pearl River	26-Aug-2003	MISSING	Y
SAP-PROC-008	002	SAP R/3 User Administration	08-Nov-2003	MISSING	Y
SAP-TPOSTPR	001	WM: Transfer Posting for Pearl River	22-Oct-2003	MISSING	Y
SAP-WMOPR	001	WM: Warehouse Management Overview for Pearl River	05-Sep-2003	MISSING	Y
SOP10104	002	Merrill Filler w/ Automated Graphic Intelligent Control Syst	03-May-2002	MISSING	Y
SOP10141	007	Packaging Consumer Health Care Products (WCH)	26-Nov-2002	MISSING	Y
SOP10165	003	Portable CT Code System Set-Up and Operation	27-Feb-2003	MISSING	Y
SOP10330	003	Omega Bottle Unscrambler Operation	29-Feb-2000	MISSING	Y
SOP10407	001	Callia Auto Trayer Set Up & Operation	12-Jul-2002	MISSING	Y
SOP10445	001	Investigation of Failed Cleaning Validation	30-Sep-2002	MISSING	Y
SOP10446	002	Protocol Preparation for Periodic Re-Qualification of Equip	30-Sep-2002	MISSING	Y
SOP10447	002	Protocol Preparation for Existing Equipment Qualification	30-Sep-2002	MISSING	Y
SOP10448	002	Execution of New Equipment Qualification	30-Sep-2002	MISSING	Y
SOP10449	002	Final Report Preparation for Equipment Qualification	30-Sep-2002	MISSING	Y
SOP10450	002	Protocol Preparation for New Equipment Qualification	30-Sep-2002	MISSING	Y
SOP10451	002	Final Report Preparation for Period Equipment Re-Qualificati	30-Sep-2002	MISSING	Y
SOP10452	002	Execution of Period Equipment Re-Qualification	30-Sep-2002	MISSING	Y
SOP10476	001	Boekels Metal Detector (Model EMD-1518) Set-Up & Challenge	07-Mar-2003	MISSING	Y
SOP10479	001	Resina U-40 Capper Set-Up & Operation	21-Oct-2002	MISSING	Y
SOP10481	000	Pace Pharma-Line Model 300 Bottle Hopper & Unscrambler Set-	19-Feb-2001	MISSING	Y
SOP10622	001	Diffuser Cleaning	20-Apr-2003	MISSING	Y
SOP10639	000	NJM Model 311 PSR Labeler with Vision System -	23-Jan-2003	MISSING	Y

1466



Wyeth - Pearl River

DATE 27-Feb-2004

TIME 8:54:56 AM

PAGE 4

# MISSING REQUIREMENTS

## By Employee

Report MISSEM

Name			Department/ Eff. Date	Status	Req.
		Set-Up and Op			
SOP20001	001	Corporate Policy Document Processing	15-Jul-1998	MISSING	Y
SOP20014	012	Packaging Audit and Destruction	23-Jun-2002	MISSING	Y
SOP20024	003	NJM 350 TSR Labeler Set-Up & Operation	22-Dec-1999	MISSING	N
SOP20028	010	Temperature and Humidity Recorder Usage	09-Jun-2003	MISSING	Y
SOP20036	004	Point-Of-Use Hose (Purified Water System) Maintenance	15-Aug-2003	MISSING	Y
SOP20046	001	Electronic Records & Signatures	21-May-1999	MISSING	Y
SOP20057	006	Container Monitoring	14-Apr-2003	MISSING	Y
SOP20058	008	Labeler Detection System Verification	05-Feb-2003	MISSING	Y
SOP20097	001	Heat Induction Cap Sealers Setup & Operation	30-Jul-1999	MISSING	N
SOP20101	002	Sealing and Applying Shipping Carton Label to Sh	17-Feb-2003	MISSING	Y
SOP20115	005	In Process Finishing Order Weekend/Holiday Shut Down	13-Apr-2003	MISSING	Y
SOP20131	004	Questionable/Unsatisfactory Components or Finished Goods	29-Sep-2000	MISSING	Y
SOP20135	003	Cleaning Between Product String Guideline - Manufacturing/Pa	30-May-2003	REVISION	Y
SOP20165	007	Vacuum Cleaner Use	30-Nov-2001	MISSING	Y
SOP20173	007	Shortage Requisition (LPR 905) - Literature	30-Nov-1999	MISSING	Y
SOP20185	007	Finished Counts/Stacking Pallets	31-Oct-2000	MISSING	Y
SOP20195	004	Pearl River Consumer Healthcare/Pharmaceutical Quality Council	31-Mar-2003	MISSING	Y
SOP20229	001	Procedure for Cleaning Mops, Buckets, Brooms and Dust Pans	09-Jun-2003	MISSING	Y
SOP20265	000	Solid Dosage Bottle Packaging Line Clearance and Cleaning	27-Sep-2002	MISSING	Y
SOP20272	002	Ideal Bundler & Pack-All Heat Tunnel Setup and Operation	02-May-2003	MISSING	Y
SOP20284	000	Key Control for Literature Security Cages in Packaging and O	21-Dec-2001	MISSING	Y
SOP20303	000	Prevention of Cross-Contamination in Corridors During Equipm	28-Jun-2002	MISSING	Y
SOPA-007	008	Converted to PPG-00005236Annual Product Evaluation	26-Dec-2001	MISSING	Y
SOPA-039	000	Inspectional Observation Verification Process	31-Dec-2001	MISSING	Y
SOPB733-109	005	Line Check In	15-Nov-2002	MISSING	Y
SOPB733-114	004	Preparation & Use of Non-Production Line Tria	12-Jun-2003	MISSING	Y
SOPM733-010	007	Packaging area Lock Up	31-Jan-2001	MISSING	Y
SOPM733-016	004	Rebulk Transfer and Return Bulk	24-Jul-2001	MISSING	Y
SOPM733-031	006	Work in Process Handling	30-Nov-2000	MISSING	Y
SOPM733-064	008	Pre-making,Prelabel & On-line Coding of Shipping Cartons	26-Oct-2001	MISSING	Y
SOPP-010	002	The Pilot Batch	27-Dec-2002	REVISION	Y
SPIPR2K-104	003	Required OSHA Inspections	11-Apr-2003	MISSING	Y
SPIPR2K-105	003	Accident Investigation Procedures	23-Aug-2002	MISSING	Y
SPIPR2K-201	004	Safety Work Permit Program	01-Oct-2002	MISSING	Y
SPIPR2K-402	003	Hazard Communication Program	12-Apr-2002	MISSING	Y
SPIPR2K-412	003	Lead Management Program	28-Jun-2002	MISSING	Y
SPIPR2K-707	003	Environmental Permit/Approval Procurement Procedure	11-Oct-2002	MISSING	Y
SPIPR2K-712	002	Response to Volatile Organic Compound (VOC) Leaks	19-Mar-2002	MISSING	Y



**MISSING REQUIREMENTS  
By Employee**

DATE 27-Feb-2004

TIME 8:54:56 AM

PAGE 5

Report MISSEM

Name	Department/ Eff. Date	Status	Req.
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**Total By Employee: 149****Total Courses: 149**

\*\*\* End of Report \*\*\*



**Summary Of Findings – Howard Henry (4/7/04)**

**Howard Henry:**

- Racial Discrimination due to a perceived demotion of position
- Engineer has a perceived higher level of skills vs packaging supervisor since that is an entry-level area and most people do not have degrees.
- Followed chain of command
- Believes that the message to him has been inconsistent which has caused him to question why the change
- Previous rating has been 3 in 2003 and a 4 in both 2002 & 2001
- Believes rating caused him to be moved and thinks that rating is unfair.
- Felt that his career has been ruined
  - Values not followed
  - Negative perception on floor
  - Allowed to get out of hand
- Believes that he can not trust people in organization – went to management out of respect – gave them an opportunity to do the right thing
- Wanted to build an organization that everyone had opportunities – build for the future
- Would like a package to do something else

**Joanne Rose:**

- Reviewed Org Cascade
- Names and Performance Rating was on each sticky
- H. Henry was not picked for a position right away
- Several issues she was aware of about performance and ability to get things done on time
- W. Wardrop changed review to reflect in out from H. Henry in January
- H. Henry has been disruptive to organization – going around and talking to people about situation

**Walter Wardrop:**

- Managed H. Henry for past 3 years
- Reviewed process of Org Cascade
  - H. Henry name on the wall most of the day
  - Selected for 3<sup>rd</sup> shift for packaging supervisor
  - Got this changed to 1<sup>st</sup> shift
  - Believes that jobs are equal in level, one manages people the other is an individual contributor role.
- Believes that manufacturing and packaging must work hand in hand and one can not live without the other
- 2003 Performance Review
  - Did not go well
  - Unhappy with rating

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D 000682**

- Used own observations and mid year review since no self appraisal was provided
- Perception from others that H. Henry did not have a sense of urgency to get things done.
- Difficult year for Howard caused a 3 rating
- No special projects, came in did his job.
- Combined performance review discussion with Cascade result and notification of his new role.
  - Cause that job assignment and rating was related
- Org Cascade caused people to think about the change, were they retained or pushed out....level of interpretation by people caused issues
- Org Cascade was an opportunity to provide cross pollination of people
- Assoc. Directors went into the meeting with a perceived 'A' team and had to negotiate for who was on their team
- Believes that managers did not pay attention to ratings of people, own perception or discussed the people with others in room

**Mike McDermott:**

- Org Cascade Champion
  - Cascade started with the process to get the product out the door then structure was built around this.
  - Drove for a cross pollination of resources to develop people and allow people to work outside of area to improve processes
- Two Sessions with H. Henry
  - Session 1
    - H. Henry describing situation and why he felt he was discriminated against
    - M. McDermott described how Org Cascade was set up and drivers for the process. Explained that the opportunity was one to help build skills
    - Offered to help him find something else if he did not want to be in packaging – H. Henry refused the assistance
    - Advised H. Henry that he could write a rebuttal to review
    - Agreed to spend time reviewing the performance review
  - Session 2
    - Reviewed findings and advised H. Henry that he concluded that he was a 3 performer. Stated in his Mid Year review
    - Circled around issue and revisited the decision to cross-pollinate people and that this was not a demotion.
- Acknowledged that Packaging and Warehouse areas are places that people do not see as a good place to be
  - Entry level perception
  - Mike started in packaging himself
  - Moved B. Bracco into warehouse area, not singled out Howard

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**D 000683**

Bob Bracco:

- Reviewed Org cascade process
- Sticky paper of names was color coded based upon rating from current year
- Opinion - Interesting and Offensive process
  - Interesting that it was an ego boast because you were playing chess with people's lives
  - Offensive because that people were reduced to a sticky and assumptions were sometimes based on the perception of the color of the sticky your name was on
- H. Henry's name was on the board all day and they tried to find him a role to fit into. Not selected as an engineer due to the competition and perception of people in the AD roles
- Perception of packaging
  - Death by tedium
  - Tough to keep people motivated
  - Driven by minutes and seconds
  - Not a fun place
  - Entry level – high turnover
- Logistics not well perceived as well, but agreed that it was an opportunity to learn a part of the business that he was not a part of...stepping stone for a Directors position.
- Had discussions with H. Henry
  - Perceived as a mentor to Howard
  - Discussed position
    - May not agree with the change but role will help resume for future opportunities
    - Raising this and keeping after it will kill your career
    - Need to separate your review from org cascade
      - No one retained you in production – don't dwell on it
      - May not be career path but could help you go where you want
  - H. Henry always linked the reason for the position was due to his rating and not for anything else
  - Follow-on conversations were philosophic in nature
- Noticed that H. Henry would be discussing this with people on the floor.

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**D 000684**



**Subject:** Re: Monthly Summary (July-2005)

188



Change complete. Closure documents submitted 7/19/05.  
Commitment closed 7/20/05.

- o Commitment PR #90042: Evaluate the feasibility of re-engineering the lock-in pin on valve
  - Due date: 9/20/05
  - Vendor contacted to provided plan and quote to redesign the valve
  - 7/26/05: Quote received
  - Vendor contacted about quote.
  - 8/2/05: Memo written assessing quote and feasibility of redesign proposal.
  - Documents submitted for closure (8/3/05).
  - Closed (8/3/05)
- o Commitment: PR# 107328 "Evaluate possibility of putting a door sweep on doors":
  - Due date 9/08/05.
  - WO# 1087975 initiated 6/9/05 to investigate possibility of installing a door sweep.
  - Investigated by carpenter. Door sweeps already in place. Gaskets replaced. Full length curtains installed
  - WO completed: 7/18/05
  - Completed WO submitted for closure (7/19/05)
  - Commitment closed 7/20/05.
- o PR #111134: CTC By-Pass Training"
  - Due date: 7/29/2005
  - All CTC operators trained on the By-Pass Training (7/21/05).
    - Midnight shift: 6 am; Day Shift: 7:30 am; Afternoon Shift: 3:15 pm.
  - Iso-train documents scanned into Trackwise for closure.
  - Forwarded and closed by QA (7/25/05)
- Monthly PMO (Status and Completion):
  - o Performed the following duties to complete this task
    - Create spreadsheet (07-08-2005).
    - Track PMO, sign off and completion for the month.
    - Sign off completion percentage: 85.7%
- Change Control Information:
  - CCP 2004-1168: "Comprima Project-Modification of Compression Room W (112-310)"
    - Initiated: 8/16/2004 (Joe Torres)
    - Contacted vendor for updated coil and AHU documents. Faxed documents to vendor.
    - Received faxed documents from vendor on 10-09-04
    - Original closure due date: 3/1/2005
    - Amendment closure due date: 7/18/2005
    - CCP Closed: 7/18/2005
  - CCP 2005-0397 "Stokes 754 Motor Change"
    - Initiated: 04/07/2005 (Emergency CCP submitted)
    - Approved: 04/18/2005
    - Closure due date: 7/18/2005
    - CCP Closed: 7/18/2005.
  - CCP 2005-0510 "Installation of 3/16" Screen for Ajax Shaker"
    - Initiated: 5/20/2005 (Emergency CCP submitted)
    - CCP walked around. Approved in one day.
    - Approved: 5/20/2005
    - Original closure due date: 6/3/2005
    - Amendment closure due date: 8/31/2005
    - CCP Closed: 7/21/2005
  - CCP 2005-0672 "Ajax Shaker" Buna-N Nitrile Rubber.
    - Initiated: 7/07/2005. Verbal approval (7/6/2005)-G. Keaney
    - Approved: 7/11/2005
    - Closure due date: 11/11/2005
    - CCP closed: 7/29/2005
- Investigated Compressed Air 100 Complex Outage Request:

- o Discussed situation with Glen Powers and Sean McGarvey (temp supervisors). Both stated that PPU#1 compression was down. PC#9 running (G. Powers). Unit stopped (Low air alarm), shut off by operator, restarted, no product impact.
- o Discussed situation with Lou Baldi (PPU#3 supervisor). Stated that PPU#3 compression was down. PC#1 running. Unit shut down, stopped by operator, restarted, no product impact.
- o Response e-mailed sent @ 8:13 pm.

- Special operator requests:

- o Increase roller protection for drum carts used in CTC#1 (7/20/05)
  - Requested by operator J. Rosado. Need to mimic design of drum carts used in CTC#2.
- WO#1097287 initiated to fix stainless steel plate.

**From:** Howard Henry  
**To:** Espejo, Andrew  
**Date:** 8/30/2004 5:25 PM  
**Subject:** Monthly Summary (08-04)

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Good afternoon Andrew,

Below is a brief summary of some of the tasks achieved during the month of August. Thank you and please contact me if you have any questions.

Howard

**Monthly Summary:**

- As project manager for the Bin Storage & Bin Warehouse projects:
  - Conducted meeting to review material project flow.
  - Meet with Ram Shankar (project engineer) to establish project parameters
  - Received confirmation from various departments designating representatives to attend project meetings (Max Katz-Safety, Miraz Chowdury-Tech. Service, Sal Calautti-QA).
- Assisted in establishing audit responses to GCA audit. One key response was calling the weekly CTC use of water to remove dust build up on the baffles a process enhancement and not a cleaning procedure. The coater is not considered clean until it is sprayed/washed with purified water.
- Contacted Dornier about "V" shaped cleats. Manufacture stated the cleats might not be sanitary.
- Conducted Combined Project Overview Meeting with maintenance.
  - Received PMO and Vib/Lub list.
  - Lists will be reviewed and discussed weekly meeting.
  - Progress made weekly. All projects on schedule to be completed before due dates.
- Conducted SOI Training with Rich Morgan.
- Trained midnight shift and day shift operators on 8K Littleford-Single Pass CTC SOI.
- Facilitated compressor check with Nikki Patel.
- Attended Work Order & PMO weekly schedule meetings.
- Troubleshooted CTC pan motor fault. (8-19-2004)
- Reviewed and signed assessment forms. Ref# PRP040 and PRP039 for 21CFRPart 11 assessment team.
- Executed Final Calibration PMO for the CTC Single Pass Project (8-18 thru 8-23-04)

- Tracked monthly PMO completion.
- Approved six SOPs. All SOPs completed before the revised target deadlines.

Goals for next month:

- Spend time on the floor with set-up workers troubleshooting and fixing various Stokes compression Machines.
  - Take a MS Project class and utilize to track projects.

Howard Henry  
Production Engineer  
Wyeth Pharmaceuticals  
Consumer Health Division  
401 N. Middletown Rd.  
Pearl River, NY 10965  
(845)-602-4843- Office  
(845)-602-3181-Fax

- Littleford 10K Plough Repair:
  - Ploughs ground down to repair wholes found in upper arc plate.
  - Provided coverage during plough repair on Saturday, 9-18-04.
- Littleford 8K Safety Upgrade:
  - Inquired about installation of Fike canisters at the request of Jim Fleming.
    - Fike Corporation will do start-up. Installation done by outside contractor.
  - Provided coverage for plough repairs and communicated progress of repair to group, 9-22-04
- Gap Tile Analysis Project:
  - Purpose: Action item based on findings from the GCA Audit. Production area rooms must be analyzed for gaps in ceiling tiles, around edges and around lights.
  - Developed spreadsheet for capturing data, conducting the study, and reporting the results (9-7-04).
  - Assessed areas on the third and fourth floors 9-10 and 9-11-04.
  - E-mailed Gap Analysis Report to Chris Defeciani. (9-15-04).
- Courses:
  - Attended Project Management Course. (9-9 and 9-10-04)
  - Attended COM-02/COM-03 "Investigation and Root Cause Analysis" (9-15-04)
  - Attended Water System Training. Trained on PPG 00001271, PPG 00001019, PPG 00002133, PPG-00001266. (9-29-04)
  - Attended GXPharma courses GXP-COUP, APUP and REUP (9-23-04)
- Manufacturing Support:
  - Provided documentation to compliance specialist Jacqui Hibbert in order to help close and investigate commitments PR# 65008, 68228, 65364, and 65006. (9-13-04)
  - Investigated and e-mailed supervisor Manny Rivera regarding an explanation to the spray gun wet tablet occurrence in the CTC. (9-15-04)
  - Provided lock core and keys to Central Storage Set-up workers for oil room 120-320B. Fixed damaged door so that door would be able to remain locked. (9-27-03)
- Combined Project:
  - Meeting #5 held 9-17-04
    - Formal discussion of classification of GMP critical instruments.
      - Control loops will be tested as a complete unit.
      - Input sources, PLCs and Output control will be dubbed critical.
      - Transmitters and transducers considered non critical GMP Instruments.
  - Meeting #6 held 9-28-2004
    - PMOs will be formally replaced by job plans. Maximo will automatically generate work orders for equipment maintenance.
    - Instrumentation PMO(s) will be controlled by CALMAN (paperless system)
    - Equipment Classification: SOP 40355 will be updated. Will include better equipment classification definitions.
- Project List Time-line sent to Andrew Espejo utilizing MS Project for review on 9-15-04

- Conducted Material Logistics Flow Meeting on 9-14-04.
  - Concluded this meeting establishing the material flow pattern for product and bin movement
  - Meeting minutes written. Forwarded on 9-16-04.
- Conducted Bin Storage/Bin Warehouse Project Meeting on 9-14-04.
  - Established final design for Project Scope document approval.
  - Meeting minutes written. Forwarded on 9-18-04
  - Project document circulated. Reviewed, signed and sent to QA for approval (9-23-04)
- Set-up PMO of 5th floor dry room Air Handler Unit on 9-17-04 by performing the following tasks:
  - Inspected Area with refrigeration mechanic James Royster
  - Inspected room for raw materials and temperature and humidity readings.
  - Scheduled to have materials temporarily moved from the 5th floor to the 3rd floor dry room until PMO is complete.
  - 9-18-04: Reactivation air temp low at 80C. Called in plumber. Charlie Petrosky repaired steam traps.
  - 9-20-04: Had material returned to 5th floor.
- 21CFRPart 11 Compliance Project:
  - Conversation with consultant Tim Billings on 9-17-04 consisted of the following:
    - Developed strategy to make CTC#1 and CTC#2 21CFRPart 11 compliant by possibly adding a Eurotherm Chessell Chart Recorder to the system
    - Expressed concern of the ability of the system to track all necessary parameters (Air flow, solution flow, weigh belt speed, faults, alarms, etc...).
    - Tim will investigate the recorder's ability and will update the Remediation and Validation Plans for CTC#1 and CTC#2 to include the chart recorder suggestion.
  - Assisted consultant Michelle Kolenski in understanding the production flow, equipment utilization and Fette computer batch record retention cycle. (9-28-04)
  - Discussed the remediation plan document with Tim Billings. The wording "Major inadequacies in validation documentation against current PPG SOP requirements", found on pages 11, 14-18 will be changed and will reference the PPG document number. (9-29-04)
  - New remediation plan submitted by Tim Billings containing better wording to replace the statement, "Major inadequacies...". Signed document and forwarded to Chris Defeciani. (9-30-04)
- Forwarded SOP Status List and Departmental Effective SOP List to Andrew Espejo. Documents discussed during August monthly 1 on 1
  - Documents to be completed by 9-30-04
  - Documents forwarded on 9-30-04
- Scale Frequency Report:
  - Project goal is to reduce the frequency of scale calibrations.
    - Received spreadsheet from Mike Aboyoun on 9-7-04. Spreadsheet contained all D640 scales.
    - Reviewed and scrutinized list.
    - Forwarded recommendations and assessment to Mike on 9-17-04.
- Commitment# 69826 "Bin valve Knob Remediation":
  - Communicated job scope and scheduling needs to supervisory staff. (9-18-04)
  - Scheduled project scope meeting with Dan Dooley and Jim Fleming. (9-21-04)
  - Job executed (9-21-04)
- Scheduled compressed air shutdown for engineer Hugh Syme.
  - CTC compressed air line shutdown scheduled for Monday, September 27th 2004.
- Monthly PMO (Status and notification):
  - Performed the following duties to complete this task
    - Create notification spreadsheet
    - Sent notifications on various dates throughout the month to inform maintenance of PMO completion progress (9-21-04, 9-28-04, 9-30-04).
- Assisted Excer Zayas with the investigation of the demolition of previous Sodium Selenate/Liquid and Ointment Area
  - Researched old change control information. Found CCP 2001-1301. (9-30-04)
  - Information reviewed and copied to assist investigation (9-30-04)
- Change Control Information:
  - Closed CCP 2004-868 on 9-16-2004. (Due date 9-30-04)
  - Closed CCP 2004-1041 (8-26-04). (Due date: 10-29-04)
  - Closed CCP 2004-0868 (9-16-04). Due date: 9-30-04
  - Initiated CCP 2004-1299: New CTC#2 equipment 9-22-04
    - Approved: (9-27-04)
  - Initiated CCP 2004-0965: Cancellation of CCP 2004-0965 (9-23-2004)
    - Canceled: (9-27-2004)
  - Change control documents submitted to close CCP 2004-0432 initiated by Aladin Alkhawam (9-30-04).
- Scheduled shutdown of Air Handler 1.7 located in B130/1st: Tablet Compression 120/3rd Floor
  - Coordinated shutdown with Jerry Perioli (9-21-2004)

- o Shut down notice sent on 9-23-2004
- SOP Documentation Approval/Obseletion:
  - o E-mailed SOP status to Chris Defeciani. (9-22-2004)
  - o Assisted Technical Writer Amani Murray in understanding information in PPG 00017421 "Littleford 10K Blending and Operation". (9-28-2004)



**From:** Howard Henry  
**To:** Espejo, Andrew  
**Date:** 11/5/2004 7:28 PM  
**Subject:** Summary (10-04)

Good evening,

Below is a brief summary of some of the tasks achieved during the month of October. Thank you and please contact me if you have any questions.

Howard

[illegible]

**Monthly Summary:**

- Littleford 8K & 10K Jog Timer Speed determination:
  - Contacted vendor to determine best course of action to save motor
  - Set up meeting to discuss 8K motor shut down issues
  - Observed batch unloading process
  - Communicated information via email to entire staff
- Courses:
  - Attended SFT-413 Maximo Delta Training. (10-04-04)
    - Attended PPG 00002508 "GMPHarama EDMS Application and Overview". (10-20-04)
    - Attended Water System Training. Trained on PPG-00001066, PPG-00001068 and PPG-00007495.
- Manufacturing Support:
  - Explained to QA manager Farooq Moatter, along with compression supervisor Jim Fleming, the details of the reinforcing and hardwiring of electronic connections for the Fette 3200 compression machines. (10-5-04)
  - Provided supervisor coverage of PPU#1 operators during the absence of supervisor Rick Morgan and Manny Rivera. (10-5-04)
    - Established Train#1 daily schedule with Joe Torres and Tony Leonty
    - Covered CTC and inspection. Continued to perform engineering duties.
    - Entered request for Unnico to clean room 120-575 (Littleford Blending Room) so that the room could be painted on 10-6-05.
  - Provided Blender Timer Report Printouts for the following equipment (10-08-04):
    - Tote Blender (09-27-04: 5 min blend- 11:16 am - 11:21 am)
      - Requested by: Bill Shafer
      - Batch #: Sponge Bob 45782-A97696
    - Drum Roller (09-03-04: 30 min blend- 3:48 pm - 4:18 pm)
      - Requested by: Skip Gremli
      - Batch #: EC#1-08730-A93407
    - Gemco 75 Slant (09-03-04: 30 min blend- 7:30 pm - 7:35 pm)
      - Requested by: Paul Couto
      - Batch #: EC#1-08730-A93408
    - Gemco 30 (10-18-04: 3 min blend- 6:15 pm - 6:18 pm)
      - Requested by: Calvin Gremli
      - Batch #: Fibercon-02500-A22365
    - Littleford 8K (10-11-04: 10 min blend- 12:14 pm - 12:24 pm)
      - Requested by: Rich Morgan
      - Batch#: Centrum-04451-A96623
    - Drum Roller (10-6-04: 30 min blend- 11:44 pm - 12:14 am)
      - Requested by: Calvin Gremli
      - Batch #: EC#1-08730-A93399
    - Littleford 8K Blender (10-25-04: 10 min blend 9:54 am - 10:04 am)

- Requested by: Rich Morgan
    - Batch#: Centrum-8427-A28901
  - Littleford 8K Blender (10-25-04: 2 min blends 1:20 pm & 1:33 pm)
    - Requested by: Rich Morgan
    - Batch#: Centrum-8427-A28901
- Provided coverage for manager A. Espejo during the afternoon of 10-05-04.
- Investigated foul odor in old compression area WO#444333 (10-06-04)
  - Shutdown compression area due to odor.
  - Placed emergency work order to investigate odor.
  - Walked area with refrigeration mechanics Evin Micich and James Royster.
  - Area inspected. Odor subsided. Area reopened for production use.
- Combined Project:
  - Meeting #7 held 10-27-04
    - Formal discussion of classification of GMP critical instruments.
    - Following items will be placed by PMO: High speed doors (WA#17450), Battery Chargers (WA# 15020, 15021)
  - Assessed Fette compression machines with Jim Fleming.
    - Investigated broken punch issue (10-7-04)
    - Contacted Fette to obtain information on degree of freedom tolerance for each punch
  - Investigated damaged screen issue (10-11-04)
    - Had static charge and grounding of unit investigated (10-11-04)
      - Unit properly grounded. Static charge appeared to come from newly waxed floor.
    - Corresponded with Bob Hirsch and spoke with Fette in order to establish meeting to investigate electrical surge problem (10-12-04)
- Commitment Information:
  - GCA Commitment: PR# 69062 "Add Process Enhancement Step to PPG 0010697 "Operation of Single Pass Continuous Tablet Coater System in Manufacturing"
    - Submitted DCC (10-14-04). Old form used. Resubmitted DCC (10-21-04). DCC# RD-2004-001295.
    - Document sent for review.
    - Document reworded and will be resent for review.
- Commitment: PR# 69826 "Bin valve Knob Remediation":
  - Communicated job scope and scheduling needs to supervisory staff. (9-18-04)
  - Scheduled project scope meeting with Dan Dooly and Jim Fleming. (9-21-04)
  - Job executed (9-21-04) Job completed (10-11-04)
  - Documents Maintenance completed and submitted on 10-12-04
  - Commitment closed on 10-12-02
- Commitment: PR# 73192 "Coated Knob found in manufacturing": (10-14-04)
  - Discussed situation with Lauri Tripp and Jacqui Hibbert
  - Provided detailed information for Jacqui Hibbert to facilitate commitment closure.
- Commitment: PR# 74398 "Tether Knobs to In-feed Conveyor Assembly": (10-19-04)
  - Created WO# 445214 to Tether knobs
  - Material ordered 10-20-04
- Commitment: PR# 74601 "Chipped Die Found"
  - Discussed situation with Compliance Specialist Jacqui Hibbert (10-21-04)
    - Briefly described the nature of the compression process and the characteristics of the dies.
    - Summary of reasons for die sliver provided. Information used to help close the commitment.
- Commitment# 74794 "Carb Assist Metal Detection"
  - Received 10-21-04 from Andrew Espejo.
  - E-mailed Ray Bartolucci in order to work with someone from Technology on the project.
  - E-mailed Francis McDermott regarding expediting the protocol to validate a metal detector for Carb Assist (10-08-2004)
- E-mailed PPU#1 and Maintenance regarding the ability of installing moisture sensors in the ductwork.
  - Contacted Vector Corporation regarding the feasibility of this request. (10-15-04)
  - Vendor called for a second time on 10-18-04
- Monthly PMO (Status and Notification):
  - Performed the following duties to complete this task
    - Create notification spreadsheet (10-12-2004)
- Change Control Information:
  - CCP 2004-1404: Installation of coil in CTC-AHU#2
    - Initiated document (10-08-04)
    - Obtained previous CCP 2004-0371 initiated by Aladin Alkhawam as a reference.

- Contacted vendor for updated coil and AHU documents. Faxed documents to vendor.
  - Received faxed documents from vendor on 10-09-04
  - Approved (10-11-04)
- Emergency CCP 2004-1419: Temporary monitor use for Fette 3200 WA#34887
  - Discuss situation with Farooq Moatter to receive verbal approval of change (10-11-04)
  - Document submitted (10-12-04)
  - Document approved (10-18-04)
- CCP 2004-1470: Bin Storage Area/Washroom Shop Upgrade Project
  - Document submitted (10-25-04)
  - Document approved (10-26-04)
- Change control documents submitted to close CCP 2004-0432 initiated by Aladin Alkhawam (9-30-04).
  - CCP Closed 10-06-04
- Closed CCP 2004-1161 "Ajax Shaker Modification"
  - Due: 11-30-04
  - CCP closed: 10-14-04
- CTC Equipment:
  - Had Weigh belt re-calibrated in order to correct OOS gains received weeks prior (WO# 443009) -10-04-04
- CTC Single Pass Project:
  - E-mailed Lam No requested PMO number information for new CTC equipment (10-13-04).
  - New equipment (Weigh belt and Servo-lift) added to current PMOs as per CCP 2004-1299 (PMO#44014, 41185, 47179 and 41184) (10-15-04)
  - Initiated WO# 445094 in order to have the Spectrum Spray Gun Arms installed
    - Initiated 10-18-04. Approved 10-20-04.
    - E-mailed Ed White in order to have this job executed on 10-25-04.
  - Assisted Lam No in identifying and confirming information for validation protocol for the Weigh Belt. (10-20-04)
  - Assisted Lam Ngo with confirming information written in document TSEQ04153 "Schenk Accurate Weigh belt DEA 300 Weigh belt Feeder". (10-26-04 and 10-28-04)
    - Accessed process parameter and configuration screens
    - Helped Lam understand
- Resolved CTC Campaign Length issue for an 8K Littleford Centrum® Batch.
  - Requested by Andrew Espejo on 10/13/04
  - E-mailed QA representatives Paul Lucas and Farooq Moatter regarding this issue (10-14-04)
  - Response received 10/18/04
  - E-mailed Larry Tunnard regarding amending study plan TSCD02010 in order to add a statement regarding the 8K.
  - Informed by Larry Tunnard that Bob Yankanin is responsible for amending the study plan (10-20-2004). E-mailed Bob Yankanin regarding amending study plan.
  - Sridhar Venkatesan responsible for adding the 8K batch comment to the protocol. Awaiting a 25 string run to submit samples to QA for testing before adding the statement.
- Investigated increased overhead cost for Fuel, Electric, Gas Cost
  - Request made by Andrew Espejo on 10-22-04
  - E-mails sent requesting information providing the reason for the high cost of Fuel, Electric, Gas for August
  - Responses received from Calvin Gremlil and Pete Sidoti.
  - Memo forwarded to A. Espejo.
- Special operator requests:
  - Provided new Locker keys for Ray E. Johnson (10-7-04)
    - Placed Work order request with locksmith
    - Sent email message to maintenance
    - Picked up keys for Ray.



- Batch #: EC#1 8730-A99322
- Gemco Slant (11-20-04: 5 min blend- 10:55 am - 11:00 am)
  - Requested by: Paul Couto
  - Batch #: EC#1 8730-A99322
- Gemco Slant (12-10-04: 3 min blend- 7:37 am - 8:00 am)
  - Requested by: Bill Shafer
  - Batch #: EC#1 8730-A99322
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- Drum Roller (09-03-04: 30 min blend- 3:48 pm - 4:18 pm)
  - Requested by: Skip Gremli
  - Batch #: EC#1-08730-A93407
- Gemco 75 Slant (09-03-04: 30 min blend- 7:30 pm - 7:35 pm)
  - Requested by: Paul Couto
  - Batch #: EC#1-08730-A93408
- Gemco 30 (10-18-04: 3 min blend- 6:15 pm - 6:18 pm)
  - Requested by: Calvin Gremli
  - Batch #: Fibercon-02500-A22365
- Littleford 8K (10-11-04: 10 min blend- 12:14 pm - 12:24 pm)
  - Requested by: Rich Morgan
  - Batch#: Centrum-04451-A96623
- Drum Roller (10-6-04: 30 min blend- 11:44 pm - 12:14 am)
  - Requested by: Calvin Gremli
  - Batch #: EC#1-08730-A93399
- Littleford 8K Blender (10-25-04: 10 min blend 9:54 am - 10:04 am)
  - Requested by: Rich Morgan
  - Batch#: Centrum-8427-A28901
- Littleford 8K Blender (10-25-04: 2 min blends 1:20 pm & 1:33 pm)
  - Requested by: Rich Morgan

- Batch#: Centrum-8427-A28901
- Provided coverage for manager A. Espejo during the afternoon of 10-05-04.
- Investigated foul odor in old compression area WO#444333 (10-06-04)
  - Shutdown compression area due to odor.
  - Placed emergency work order to investigate odor.
  - Walked area with refrigeration mechanics Evin Micich and James Royster.
  - Area inspected. Odor subsided. Area reopened for production use.
- Combined Project:
  - Meeting #7 held 10-27-04
    - Formal discussion of classification of GMP critical instruments.
    - Following items will be placed on PMO: High speed doors (WA#17450), Battery Chargers (WA# 15020, 15021)
  - Assessed Fette compression machines with Jim Fleming.
    - Investigated broken punch issue (10-7-04)
    - Contacted Fette to obtain information on degree of freedom tolerance for each punch
  - Investigated damaged screen issue (10-11-04)
    - Had static charge and grounding of unit investigated (10-11-04)
      - Unit properly grounded. Static charge appeared to come from newly waxed floor.
    - Corresponded with Bob Hirsch and spoke with Fette in order to establish meeting to investigate electrical surge problem (10-12-04)
- Commitment Information:
  - GCA Commitment: PR# 69062 "Add Process Enhancement Step to PPG 0010697 "Operation of Single Pass Continuous Tablet Coater System in Manufacturing"
    - Submitted DCC (10-14-04). Old form used. Resubmitted DCC (10-21-04). DCC# RD-2004-001295.
    - Document sent for review.
    - Document reworded and will be resent for review.
- Commitment: PR# 69826 "Bin valve Knob Remediation":
  - Communicated job scope and scheduling needs to supervisory staff. (9-18-04)

- Scheduled project scope meeting with Dan Dooly and Jim Fleming. (9-21-04)
  - Job executed (9-21-04) Job completed (10-11-04)
  - Documents Maintenance completed and submitted on 10-12-04
  - Commitment closed on 10-12-02
- Commitment: PR# 73192 "Coated Knob found in manufacturing": (10-14-04)
  - Discussed situation with Lauri Tripp and Jacqui Hibbert
  - Provided detailed information for Jacqui Hibbert to facilitate commitment closure.
- Commitment: PR# 74398 "Tether Knobs to In-feed Conveyor Assembly": (10-19-04)
  - Created WO# 445214 to Tether knobs
  - Material ordered 10-20-04
- Commitment: PR# 74601 "Chipped Die Found"
  - Discussed situation with Compliance Specialist Jacqui Hibbert (10-21-04)
    - Briefly described the nature of the compression process and the characteristics of the dies.
    - Summary of reasons for die sliver provided. Information used to help close the commitment.
- Commitment# 74794 "Carb Assist Metal Detection"
  - Received 10-21-04 from Andrew Espejo.
  - Emailed Ray Bartolucci in order to work with someone from Technology on the project.
  - Emailed Francis McDermott regarding expediting the protocol to validate a metal detector for Carb Assist (10-08-2004)
- Emailed PPU#1 and Maintenance regarding the ability of installing moisture sensors in the ductwork.
  - Contacted Vector Corporation regarding the feasibility of this request. (10-15-04)
  - Vendor called for a second time on 10-18-04
- Monthly PMO (Status and Notification):
  - Performed the following duties to complete this task
    - Create notification spreadsheet (12-08-2004)
    - Sent notifications on various dates throughout the month to inform maintenance of PMO completion progress (12-10-04)



- Change Control Information:
  - CCP 2004-1404: Installation of coil in CTC-AHU#2
    - Initiated document (10-08-04)
    - Obtained previous CCP 2004-0371 initiated by Aladin Alkhawam as a reference.
    - Contacted vendor for updated coil and AHU documents. Faxed documents to vendor.
    - Received faxed documents from vendor on 10-09-04
    - Approved (10-11-04)
  - Emergency CCP 2004-1419: Temporary monitor use for Fette 3200 WA#34887
    - Discuss situation with Farooq Moatter to receive verbal approval of change (10-11-04)
    - Document submitted (10-12-04)
    - Document approved (10-18-04)
  - CCP 2004-1470: Bin Storage Area/Washroom Shop Upgrade Project
    - Document submitted (10-25-04)
    - Document approved (10-26-04)
  - Change control documents submitted to close CCP 2004-0432 initiated by Aladin Alkhawam (9-30-04).
    - CCP Closed 10-06-04
  - Closed CCP 2004-1161 "Ajax Shaker Modification"
    - Due: 11-30-04
    - CCP closed: 10-14-04
- CTC Equipment:
  - Had Weigh belt re-calibrated in order to correct OOS gains received weeks prior (WO# 443009) -10-04-04
- CTC Single Pass Project:
  - Emailed Lam Ngo requested PMO number information for new CTC equipment (10-13-04).
  - New equipment (Weigh belt and Servo-lift) added to current PMOs as per CCP 2004-1299 (PMO#44014, 41185, 47179 and 41184) (10-15-04)
  - Initiated WO# 445094 in order to have the Spectrum Spray Gun Arms installed

- Initiated 10-18-04. Approved 10-20-04.
- Emailed Ed White in order to have this job executed on 10-25-04.
- Assisted Lam Ngo in identifying and confirming information for validation protocol for the Weigh Belt. (10-20-04)
- Assisted Lam Ngo with confirming information written in document TSEQ04153 "Schenck Accurate Weighbelt DEA 300 Weighbelt Feeder". (10-26-04 and 10-28-04)
  - Accessed process parameter and configuration screens
  - Helped Lam understand
- Resolved CTC Campaign Length issue for an 8K Littleford Centrum® Batch.
  - Requested by Andrew Espejo on 10/13/04
  - Emailed QA representatives Paul Lucas and Farooq Moatter regarding this issue (10-14-04)
  - Response received 10/18/04
  - Emailed Larry Tunnard regarding amending study plan TSCD02010 in order to add a statement regarding the 8K.
  - Informed by Larry Tunnard that Bob Yankanin is responsible for amending the study plan (10-20-2004). Emailed Bob Yankanin regarding amending study plan.
  - Sridhar Venkatesan responsible for adding the 8K batch comment to the protocol. Awaiting a 25 string run to submit samples to QA for testing before adding the statement.
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